

# EXHIBIT 5

# CIBC World Markets

## Equity Research

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### Pharmaceuticals

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## Pharmacia Corporation

CLASS Flunks Out

### Investment Conclusion

- **FDA Panel Rejects Label Change.** An FDA Advisory Committee rejected the notion that Celebrex, a COX-2 inhibitor, has a better safety profile NSAIDs. PHA shares sold off (3+%) based on concerns that Celebrex's growth will stagnate without a label change. In addition, it appears unlikely that Merck's Vioxx will win a label change as well.
- **Implications of the Panel's Decision.** As we did not expect a wholesale label change both for Celebrex and Vioxx, we are not changing our 2001 sales estimates for Celebrex (\$3.6 billion) or Vioxx (\$3.1 billion). While a label change could have boosted growth near term, physicians have already embraced the safety potential.
- **Market Share Growth Is Stable.** Concern over slowing market share is likely to manifest in share price weakness. However, given the tremendous initial ramp-up of COX-2s, we're not surprised. We note that share is increasing at one percentage point per month, a similar trend observed for drugs like Lipitor and Neurontin (Pfizer).
- **Room to Grow.** Celebrex and Vioxx have yet to be fully launched in Europe and Japan, suggesting growth to come, particularly given the lack of innovation in this area. Market growth, though, is likely to be driven by more drugs (2002E). While COX-2s have slim advantages over NSAIDs, promotion and demographics should boost use.
- **Potential Share Weakness.** Shares of MRK and PHA could be pressured (MRK in particular, as the panel meets 2/8, grappling with cardiovascular inconsistencies in VIGOR's database), COX-2s will continue to generate growth. Share price weakness affords an opportunity as we believe Celebrex and Vioxx's growth trends are not likely to change materially. MRK and PHA are rated Buy.

### Rating: BUY

PHA-NYSE (2/7/2001):	\$56 1/8
52-week Range:	\$64-35 1/16
Shares Outstanding:	1.3 Billion
Float:	1 Billion Shares
Market Capitalization:	\$73 Billion
Dividend/Yield:	\$0.48/0.9%
Fiscal Year Ends:	December
Book Value:	\$4.16 per Share
2000E ROE:	0.0%
LT Debt:	\$5.3 Billion
Preferred:	Nil
Common Equity:	\$5.3 Billion

### Earnings per Share

1999 .....	\$1.11*
2000E .....	\$1.45*
2001E .....	\$1.75
2002E .....	\$2.08

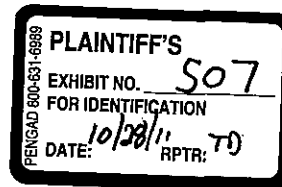
### P/E Ratio

1999 .....	50.6X*
2000E .....	38.7X*
2001E .....	32.1X
2002E .....	27.0X

\* Excludes all one-time charges and gains.

### Company Description:

Pharmacia was created through the merger of Pharmacia & Upjohn and Monsanto in 1Q00. The company markets Celebrex, a leading antiarthritic and Xalatan, for glaucoma. In 4Q00, 13.7% of Monsanto was spun-off.



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**Our quarterly EPS estimates are shown below.**

		1 Qtr.	2 Qtr.	3 Qtr.	4 Qtr.	Year
1999	Actual	\$0.26	\$0.40	\$0.21	\$0.24	\$1.11
2000E	Current	\$0.33A	\$0.47A	\$0.33A	\$0.32E	\$1.45E
2001E	Current	---	---	---	---	\$1.75E
2002E	Current	---	---	---	---	\$2.08E

**Stock prices (as of 2/07/01) of companies mentioned in this report:**

Merck & Co. (MRK-NYSE \$81.85, Buy) (1)  
Pfizer, Inc. (PFE-NYSE \$44.50, Hold)

(1) The CIBC World Markets Corp. analyst(s) who covers this company also has a position in its securities.

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**Exhibit 1**

Pharmacia Corporation: Pro Forma Income Statement By Year										
(\$ in millions, except EPS)										
	Year Ended December									
	% 2002E Chg.		% 2001E Chg.		% 2000E Chg.		% 1999A Chg.		% 1998A Chg.	
Revenue:										
Pharmaceuticals and Consumer	\$15,900	12.7%	\$14,105	14.4%	\$12,330	15.4%	\$10,681	34.9%	\$7,919	3.5%
Agriculture	5,850	5.5	5,545	2.7	5,400	2.9	5,248	23.1	4,264	36.4
Other	500	3.1	485	5.4	460	(7.3)	496	21.6	408	NM
Total sales	\$22,250	10.5%	\$20,135	10.7%	\$18,190	10.7%	\$16,425	7.4%	\$15,293	NM
Cost of sales	6,375	6.9	5,965	6.5	5,600	5.7	5,299	7.2	4,943	59.9
Gross profit	\$15,875	12.0%	\$14,170	12.5%	\$12,590	13.2%	\$11,126	7.5%	\$10,350	7.8%
Gross profit margin	71.3%		70.4%		69.2%		67.7%		67.7%	
SG&A	8,315	11.2	7,480	12.3	6,663	13.7	5,859	25.2	4,681	131.4
SG&A/sales	37.4%		37.1%		36.6%		35.7%		30.6%	
R&D	3,340	9.9	3,040	10.7	2,745	(1.5)	2,786	9.6	2,542	143.5
R&D/sales	15.0%		15.1%		15.1%		17.0%		16.6%	
EBITD	\$4,220	15.6%	\$3,650	14.7%	\$3,182	28.2%	\$2,481	(20.6%)	\$3,127	(52.2%)
EBITD margin	19.0%		18.1%		17.5%		15.1%		20.4%	
Amortization	100	(35.5)	155	(35.1)	239	(0.4)	240	(37.5)	384	122.0
Operating income	\$4,120	17.9%	\$3,495	18.8%	\$2,943	31.3%	\$2,241	(18.3%)	\$2,743	(56.9%)
Operating margin	18.5%		17.4%		16.2%		13.6%		17.9%	
Interest & other income, net	(125)	NM	(135)	NM	(247)	NM	(180)	NM	94	(170.7)
Pretax income	\$3,995	18.9%	\$3,360	24.6%	\$2,696	30.8%	\$2,061	(27.3%)	\$2,837	(54.5%)
Taxes	1,199	18.9	1,008	24.1	812	29.1	629	(30.7)	908	201.6
Tax rate	30.0%		30.0%		30.1%		30.5%		32.0%	
Net income, continuing ops	\$2,797	18.9%	\$2,352	24.8%	\$1,884	31.5%	\$1,432	(25.8%)	\$1,929	(67.5%)
Net margin	12.6%		11.7%		10.4%		8.7%		12.6%	
Consolidated EPS	\$2.14	18.7%	\$1.80	24.1%	\$1.45	30.1%	\$1.11	NM	\$1.52	(68.4%)
Minority Interest	0.06	20.0	0.05	NM	0.00	NM	0.00	NM	0.00	NM
Earnings per share	\$2.08	18.7%	\$1.75	20.7%	\$1.45	30.1%	\$1.11	NM	\$1.52	NM
Discontinued operations	0.00	NM	0.00	NM	(0.02)	NM	0.06	NM	0.00	NM
Earnings per share	\$2.08	18.7%	\$1.75	22.4%	\$1.43	21.8%	\$1.17	NM	\$1.52	NM
Diluted shares outstanding	1,308.0	0.2	1,306.0	0.6	1,298.6	1.2	1,283.5	NM	1,270.0	NM

Source: Pharmacia Corporation, CIBC World Markets estimates.

Source: Pharmacia Corporation, CIBC World Markets estimates.

Exhibit 2

Pharmacia Corporation: Product Revenues By Year								
(\$ in millions)								
Revenues:	Year Ended December							
	2002E	% Chg.	2001E	% Chg.	2000E	% Chg.	1999A	% Chg.
<b>Focus Products</b>								
Celebrex	\$4,275	22.1%	\$3,500	37.3%	\$2,550	73.4%	\$1,471	NM
Camptosar	975	39.3	700	52.2	460	56.8	293	51.2
Detrol	730	20.7	605	33.0	455	38.3	329	163.2
Zyvox	220	91.3	115	155.6	45	NM	0	NM
<b>Oncology</b>								
Pharmarubicin	160	0.0	160	(8.6)	175	(12.1)	199	12.4
Adriamycin	50	(9.1)	55	(8.3)	60	(7.0)	65	(3.7)
Ellence	60	50.0	40	166.7	15	NM	7	NM
Aromasin	75	50.0	50	100.0	25	NM	0	NM
<b>Inflammation</b>								
Cytotec	\$20	(20.0%)	\$25	(37.5%)	\$40	(50.0%)	\$80	(40.7%)
Arthrotec	200	(20.0)	250	(18.0)	305	(10.3)	340	(1.7)
Daypro	40	(38.5)	65	(48.0)	125	(43.7)	222	(27.2)
Parecoxib	225	309.1	55	NM	0	NM	0	NM
Valedecoxib	115	NM	0	NM	0	NM	0	NM
<b>Metabolic disease</b>								
Genotropin	\$575	6.3%	\$540	8.0%	\$500	8.5%	\$461	16.7%
Fragmin	270	8.0	250	11.1	225	5.5	213	17.8
Micronase/Glynase	60	(7.7)	65	(7.1)	70	(5.1)	74	(19.8)
<b>CNS</b>								
Vestra	\$15	NM	\$0	NM	\$0	NM	\$0	NM
Xanax	275	(9.8)	305	(4.7)	320	(0.1)	320	(0.2)
Mirapex	85	(5.6)	90	5.9	85	4.4	81	66.1
<b>Infectious disease</b>								
Cleocin	\$395	3.9%	\$380	4.1%	\$365	6.5%	\$343	9.2%
Vantin	35	(12.5)	40	(11.1)	45	(5.1)	47	(8.8)
Lincocin	35	(12.5)	40	(20.0)	50	0.4	50	(2.4)
<b>Genitourinary</b>								
Depo-Provera	\$255	(1.9%)	\$260	2.0%	\$255	1.2%	\$252	11.0%
Provera	80	(5.9)	85	(5.6)	90	(5.1)	95	(5.2)
<b>Cardiovascular</b>								
Calan	\$20	(20.0%)	\$25	(28.6%)	\$35	(30.0%)	\$50	(28.6%)
Covera HS	190	2.7	185	5.7	175	8.7	161	98.8
Spironolactone	150	(14.3)	175	(12.5)	200	(10.7)	224	12.0
<b>Other</b>								
Medrol	\$250	(7.4%)	\$270	(1.8%)	\$275	(7.5%)	\$297	12.6%
Xalatan	1,075	15.0	935	29.9	720	41.9	507	52.8
Ambien	810	8.0	750	11.1	675	29.1	523	14.2
<b>Total Pharmaceuticals</b>	<b>\$15,225</b>	<b>13.4%</b>	<b>\$13,430</b>	<b>15.1%</b>	<b>\$11,670</b>	<b>16.7%</b>	<b>\$9,996</b>	<b>30.8%</b>
<b>Consumer Health Care</b>	<b>\$675</b>	<b>0.0%</b>	<b>\$675</b>	<b>2.3%</b>	<b>\$660</b>	<b>(3.6%)</b>	<b>\$685</b>	<b>0.3%</b>
Rogaine	130	(7.1)	140	3.7	135	(2.9)	139	4.5
Nicorette	225	2.3	220	2.3	215	(8.1)	234	9.9
<b>Animal Health</b>	<b>\$500</b>	<b>3.1%</b>	<b>\$485</b>	<b>5.4%</b>	<b>\$460</b>	<b>9.3%</b>	<b>\$421</b>	<b>3.2%</b>
<b>Agriculture</b>	<b>\$5,850</b>	<b>5.5%</b>	<b>\$5,545</b>	<b>2.7%</b>	<b>\$5,400</b>	<b>2.9%</b>	<b>\$5,248</b>	<b>23.1%</b>
<b>Total Product Revenue</b>	<b>\$22,250</b>	<b>10.5%</b>	<b>\$20,135</b>	<b>10.7%</b>	<b>\$18,190</b>	<b>10.7%</b>	<b>\$16,425</b>	<b>7.4%</b>
Source: Pharmacia Corporation, CIBC World Markets Corp. estimates.								

**Exhibit 3**

Merck & Co.: Income Statement By Year										
(\$ in millions, except EPS)										
	Year Ended December									
	2002E		2001E		2000A		1999A		1998A	
Revenue:		% Chg.		% Chg.		% Chg.		% Chg.		% Chg.
Pharmaceuticals	\$25,075	10.7%	\$22,655	12.0%	\$20,225	15.7%	\$17,480	14.3%	\$15,297	12.1%
Medco	27,750	18.0	23,520	16.8	20,140	32.2	15,235	31.3	11,602	22.9
<b>Total sales</b>	<b>\$52,825</b>	<b>14.4%</b>	<b>\$46,175</b>	<b>14.4%</b>	<b>\$40,365</b>	<b>23.4%</b>	<b>\$32,715</b>	<b>21.6%</b>	<b>\$26,898</b>	<b>13.8%</b>
Cost of sales	31,125	17.4	26,520	18.2	22,444	28.0	17,534	25.9	13,925	18.1
Gross profit	\$21,700	10.4%	\$19,655	9.7%	\$17,922	18.1%	\$15,181	17.0%	\$12,973	9.5%
Gross profit margin	41.1%		42.6%		44.4%		46.4%		48.2%	
SG&A	7,640	10.9	6,890	11.7	6,168	18.6	5,200	15.3	4,511	4.9
SG&A/sales	14.5%		14.9%		15.3%		15.9%		16.8%	
R&D	3,000	12.1	2,675	14.1	2,344	13.3	2,068	13.6	1,821	8.2
R&D/sales	5.7%		5.8%		5.8%		6.3%		6.8%	
<b>Operating income</b>	<b>\$11,060</b>	<b>9.6%</b>	<b>\$10,090</b>	<b>7.2%</b>	<b>\$9,410</b>	<b>18.9%</b>	<b>\$7,912</b>	<b>19.2%</b>	<b>\$6,641</b>	<b>13.2%</b>
Operating margin	20.9%		21.9%		23.3%		24.2%		24.7%	
Interest & other income, net (a)	355	(30.4)	510	22.6	416	(41.2)	707	18.9	595	(0.6)
<b>Pretax income</b>	<b>\$11,415</b>	<b>7.7%</b>	<b>\$10,600</b>	<b>7.9%</b>	<b>\$9,826</b>	<b>14.0%</b>	<b>\$8,620</b>	<b>19.1%</b>	<b>\$7,235</b>	<b>12.0%</b>
Taxes	3,425	5.9	3,233	7.7	3,002	10.0	2,729	37.2	1,989	7.6
Tax rate	30.0%		30.5%		30.6%		31.7%		27.5%	
<b>Net income</b>	<b>\$7,991</b>	<b>8.5%</b>	<b>\$7,367</b>	<b>8.0%</b>	<b>\$6,824</b>	<b>15.8%</b>	<b>\$5,891</b>	<b>12.3%</b>	<b>\$5,246</b>	<b>13.7%</b>
Net margin	15.1%		16.0%		16.9%		18.0%		19.5%	
<b>Earnings per share, diluted</b>	<b>\$3.58</b>	<b>11.0%</b>	<b>\$3.22</b>	<b>11.2%</b>	<b>\$2.98</b>	<b>18.5%</b>	<b>\$2.45</b>	<b>13.9%</b>	<b>\$2.15</b>	<b>15.0%</b>
Diluted shares outstanding	2,233.0	(2.3)	2,284.7	(2.9)	2,353.2	(2.2)	2,407.0	(1.4)	2,441.2	(1.1)

(a) Includes goodwill and net profits (loss) from joint ventures.

Sources: Merck & Co., CIBC World Markets estimates.

**Exhibit 4**

Merck & Co.: Product Revenues By Year										
(\$ in millions)										
Revenues:	2002E	% Change	2001E	% Change	2000A	% Change	1999A	% Change	1998A	% Change
<b>Focus Products</b>										
Zocor	\$5,605	5.0%	\$5,340	1.1%	\$5,280	17.5%	\$4,495	13.9%	\$3,945	10.5%
Cozaar	2,315	15.8	2,000	16.6	1,715	23.8	1,385	30.7	1,060	55.7
Fosamax	1,750	15.9	1,510	18.4	1,275	22.0	1,045	34.8	775	45.7
Singulair	1,795	38.1	1,300	51.2	860	72.0	500	157.7	194	NM
Vioxx	4,305	41.1	3,050	41.2	2,160	357.6	472	NM	0	NM
<b>Cardiovascular</b>	\$9,980	(0.4%)	\$10,025	(5.1%)	\$10,560	8.5%	\$9,730	9.2%	\$8,907	4.5%
Vasotec	735	(21.0)	930	(48.0)	1,790	(22.3)	2,305	(4.0)	2,400	(4.4)
Mevacor	150	(50.0)	300	(42.3)	520	(13.3)	600	(19.5)	745	(32.1)
Prinivil	900	(26.8)	1,230	14.4	1,075	31.9	815	18.1	690	17.9
Aggrastat	230	27.8	180	38.5	130	62.5	80	247.8	23	NM
<b>Anti-infectives</b>	\$1,085	(2.3%)	\$1,110	(5.1%)	\$1,170	(8.6%)	\$1,280	(11.8%)	\$1,452	7.0%
Crixivan	380	(10.6)	425	(19.8)	530	(20.3)	665	(1.5)	675	16.0
Primaxin	675	3.1	655	8.3	605	5.2	575	9.5	525	(0.9)
<b>Metabolic</b>	\$4,740	15.5%	\$4,105	12.3%	\$3,655	18.3%	\$3,090	19.7%	\$2,581	21.9%
Pepoid	400	(27.3)	550	(35.3)	850	(6.6)	910	(18.0)	1,110	(5.9)
Proscar	525	5.0	500	6.4	470	5.6	445	7.2	415	3.8
Propecia	265	10.4	240	23.1	195	5.4	185	122.9	83	NM
<b>Vaccines</b>	\$870	(2.2%)	\$890	(5.8%)	\$945	9.9%	\$860	1.6%	\$847	15.4%
Hepatitis vaccines	280	(6.7)	300	(13.0)	345	15.0	300	(4.8)	315	2.6
Viral vaccines	525	1.0	520	0.0	520	6.1	490	4.3	470	17.5
<b>Other Pharmaceuticals</b>	\$8,400	28.7%	\$6,525	67.5%	\$3,895	54.6%	\$2,520	66.8%	\$1,511	65.5%
Timoptic XL	200	(13.0)	230	(9.8)	255	(13.6)	295	(7.8)	320	(9.9)
Trusopt/Cosopt	440	6.0	415	13.7	365	10.6	330	24.5	265	18.3
Maxalt	255	24.4	205	7.9	190	81.0	105	288.9	27	NM
<b>Total Pharmaceuticals</b>	\$25,075	10.7%	\$22,655	12.0%	\$20,225	15.7%	\$17,480	14.3%	\$15,297	12.1%
Medco (b)	\$27,750	18.0%	\$23,520	16.8%	\$20,140	32.2%	\$15,235	31.3%	\$11,602	22.9%
<b>Total Product Revenue</b>	\$52,825	14.4%	\$46,175	14.4%	\$40,365	23.4%	\$32,715	21.6%	\$26,898	13.8%

(a) Does not reflect discounts and rebates. These are netted in "other, net".

(b) Medco sales of Merck products are reflected in individual product sales categories.

Sources: Merck & Co., CIBC World Markets estimates.

**Exhibit 5**

Pharmacia Corporation: Selected New Product Pipeline				
Drug	Therapeutic Category: Indication	Description	Stage of Development	
			US	Europe
Vestra	CNS: depression	Norepinephrine reuptake inhibitor	Approvable	Market
Aromasin	Oncology: post menopausal breast cancer	Type 1 aromatase inhibitor	Approved	Filed
Zyvox	Infectious disease: gram positive infections	Oxazolidinone	Approved	Phase III
Xalcom	Ophthalmology: glaucoma	Prostanoid FP-r agonist & beta blocker	Approvable	Filed
Axert	CNS: migraine headache	5HT <sub>1</sub> receptor agonist	Filed	**
Celebrex (a)	Inflammation: pain (CLASS data)	COX-2 inhibitor	Filed	Filed
Parecoxib	Inflammation: pain relief	COX-2 inhibitor injectable	Filed	Phase III
Valdecoxib	Inflammation: arthritis, pain relief	COX-2 inhibitor	Phase III	Phase III
Eplerenone	Cardiovascular: hypertension, congestive heart failure	Selective aldosterone receptor antagonist	Phase III	Phase III
SenE12	Ophthalmology: macular degeneration (wet)	Photodynamic therapy	Phase III	Phase III
Camptosar (a)	Oncology: small cell lung cancer	Topoisomerase I inhibitor	Phase III	Phase III
Xalatan (a)	Ophthalmology: first line glaucoma, combination	Prostanoid FP-r agonist	Phase III	Phase III
Tifacogin	Infectious disease: sepsis	TiFP antagonist	Phase III	Phase III
Trelstar	Female Health Care: endometriosis	LHRH agonist	Phase III	Phase III
Trelstar	Oncology: advanced prostate cancer	LHRH agonist	Phase III	Phase III
TPO	Oncology: advanced non-small cell lung cancer	Thrombopoietin	Phase II	Phase II
SU5416	Oncology: solid tumors	Angiogenesis inhibitor	Phase II	Phase II
Reglixane	Metabolic: type II diabetes	Insulin sensitizer	Phase II	Phase II
Camptosar (a)	Oncology: advanced non-small cell lung cancer	Topoisomerase I inhibitor	Phase II	**
Celebrex (a)	CNS: Alzheimer's disease	COX-2 inhibitor	Phase II	Phase II
Celebrex (a)	Oncology: colon cancer	COX-2 inhibitor	Phase II	Phase II
PNU 95666	CNS: Parkinson's disease	D <sub>2</sub> agonist	Phase II	Phase II
PNU 101387	CNS: schizophrenia	D <sub>4</sub> antagonist	Phase II	Phase II
PNU 83757	Metabolic: erectile dysfunction	Calcium channel opener	Phase II	Phase II

(a) Line extension/supplemental indication.

Source: Pharmacia Corporation, CIBC World Markets estimates.



**Exhibit 6**

<b>Merck &amp; Co.: Selected New Product Pipeline</b>				
<b>Drug</b>	<b>Therapeutic Category: Indication</b>	<b>Description</b>	<b>Stage of Development</b>	
			<b>US</b>	<b>Europe</b>
Candidas	Infectious disease: candida, aspergillus infections	Glucansynthase inhibitor	Approved	Phase III
Invanz	Infectious disease: complicated infections	Carbapenem antibiotic	Filed	Filed
Fosamax (a)	Metabolic: male osteoporosis	Aminobisphosphonate	Approved	Filed
Fosamax (a)	Metabolic: once-weekly	Aminobisphosphonate	Approved	Filed
Vioxx (a)	Inflammation: rheumatoid arthritis	COX-2 inhibitor	Phase III	Phase III
Etoricoxib	Inflammation: osteoarthritis, RA, pain	COX-2 inhibitor	Phase III	Phase III
Singulair/Clarithin (b)	Respiratory: asthma/allergies	Leukotriene antagonist/antihistamine	Phase III	Phase III
Zocor/ezetimibe (b)	Cardiovascular: cholesterol lowering	Statin/cholesterol absorption inhibitor	Phase III	Phase III
Proscar (a)	Oncology: prevention of prostate cancer	5-alpha reductase inhibitor	Phase III	Phase III
Vioxx (a)	CNS: Alzheimer's disease	COX-2 inhibitor	Phase III	Phase III
KRP-297	Metabolic: diabetes	Thiazolidinedione	Phase II	Phase II
J-104132	Cardiovascular: congestive heart failure	Endothelin antagonist	Phase II	Phase II
Substance P	CNS: depression	Second generation substance P antagonist	Phase II	Phase II
MK-869	CNS: chemotherapy-induced nausea	Substance P antagonist	Phase II	Phase II
HPV vaccine	Infectious disease: human papilloma infection	Vaccine	Phase II	Phase II
Rotavirus vaccine	Infectious disease: rotaviral infections	Vaccine	Phase II	Phase II

(a) Line extension/new indication.

(b) Co-development with Schering-Plough.

Sources: Merck &amp; Co., CIBC World Markets estimates.

## Pharmaceutical Industry - EPS Estimates and Valuation

Company	Ticker Symbol	Rating	Price 02/07/01	52 Week		EPS 2000E	EPS 2001E	EPS 2002E	% EPS Growth	P/E				
				High	Low					1999A	2000E	2001E	2002E	
American Home Products Corp. (a)	AHP	B	61 2/5	65 1/4	40 1/2	1.75	1.90	2.18	2.50	13	35.1	32.3	28.2	24.6
AstraZeneca PLC (a)	AZN	H	44 46/73	52 27/73	30 32/97	1.41	1.63	1.80	1.75	8	31.7	27.4	24.8	25.5
Bristol-Myers Squibb Co. (b)	BMJ	SB	64 49/50	74 67/77	42 3/7	2.06	2.36	2.63	2.95	13	31.5	27.5	24.7	22.0
GlaxoSmithKline PLC (c)	GSK	H	53 3/4	64 40/93	45 1/4	NA	1.85	2.10	2.25	10	NM	29.1	25.6	23.9
Johnson & Johnson	JNJ	B	94 9/10	105 40/43	66 3/25	2.97	3.42	3.85	4.35	12	32.0	27.7	24.6	21.8
Eli Lilly & Co.	LLY	H	78 19/20	109	54	2.28	2.65	2.83	3.00	10	34.6	29.8	27.9	26.3
Merck & Co. (d)	MRK	B	81 17/20	96 17/25	52	2.45	2.90	3.22	3.58	12	33.4	28.2	25.4	22.9
Pfizer Inc. (e)	PFE	H	44 1/2	49 1/4	30	0.79	1.02	1.27	1.56	18	56.3	43.6	35.0	28.5
Pharmacia Inc.	PHA	B	56 3/23	64	35 3/50	1.11	1.45	1.75	2.08	14	50.6	38.7	32.1	27.0
Schering-Plough Corp.	SGP	H	50 24/25	60	30 1/2	1.42	1.64	1.88	2.14	13	35.9	31.1	27.1	23.8
Share Weighted Average														
S & P Industrials (f)	SPII		1569.19	1947.79	1454.66	58.00	60.53	62.23	64.75		27.1	25.9	25.2	24.2
S & P 500 (f)	SPX		1340.89	1553.11	1254.26	50.82	57.06	59.39	65.38		26.4	23.5	22.6	20.5

Company	Ticker Symbol	Stock Price Performance (% Change)				Net Debt (\$ Bn)	Market Value (\$ Bn)	EV to 1999A (c)			Relative P/E (SPX)			
		1 Mo.	3 Mo.	12 Mo.	YTD			Sales	EBITDA	Gross Profit	1999A	2000A	2001E	2002E
American Home Products Corp.	AHP	(3.4%)	(2.0%)	36.4%	(1.6%)	1.255	80.5	6.0	19.1	8.0	1.33	1.38	1.25	1.20
AstraZeneca PLC	AZN	(13.3)	(5.0)	20.6	(12.3)	(2.205)	78.9	5.1	17.0	6.9	1.20	1.17	1.10	1.24
Bristol-Myers Squibb Co.	BMJ	(12.1)	2.5	0.5	(9.1)	(1.183)	129.1	6.3	19.6	8.7	1.20	1.17	1.09	1.07
GlaxoSmithKline PLC	GSK	NM	NM	NM	(3.8)	1.079	163.2	12.0	35.2	15.0	NM	1.24	1.13	1.16
Johnson & Johnson	JNJ	(9.7)	4.3	11.9	(7.0)	(0.064)	134.7	4.9	18.3	7.1	1.21	1.18	1.09	1.06
Eli Lilly & Co.	LLY	(15.2)	(13.2)	20.4	(13.7)	(0.963)	86.5	8.6	23.0	10.9	1.31	1.27	1.24	1.28
Merck & Co.	MRK	(12.6)	(8.8)	6.6	(12.0)	2.801	192.8	6.0	21.6	12.9	1.27	1.20	1.13	1.11
Pfizer Inc.	PFE	(3.3)	2.3	20.3	(3.5)	2.487	283.4	10.4	27.2	12.9	2.13	1.86	1.55	1.39
Pharmacia Inc.	PHA	(8.0)	(2.3)	46.0	(6.5)	6.399	73.0	8.7	35.3	13.5	1.92	1.65	1.42	1.32
Schering-Plough Corp.	SGP	(10.2)	(2.1)	12.8	(6.1)	(1.142)	75.1	8.1	31.2	10.0	1.36	1.32	1.20	1.16
Share Weighted Average														
S & P Industrials	SPII	2.7	(4.1)	(10.5)	(6.6%)			8.4	25.7	11.4	NM	1.44	1.28	1.23
S & P 500	SPX	1.6	(1.7)	(4.5)	4.5									

(a) EPS figures are pro forma for the divestiture of agricultural (b) Pro forma EPS for the two divestitures are \$2.12 and \$2.35 (c) EPS translated @ \$1.57 (d) The CIBC World Markets analyst(s) that covers this company also has a position in its securities. (e) 1999 includes one-time items. (f) First Call estimates.

\* Actual reported EPS.

Source: CIBC World Markets Corp. estimates, Company reports, Factset, ILLX, First Call

# EXHIBIT 6

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

ALASKA ELECTRICAL PENSION  
FUND, *et al.*, On Behalf of Themselves  
and All Others Similarly Situated,

Plaintiffs,

vs.

PHARMACIA CORPORATION, *et al.*,

Defendants.

Civil Action No. 3:09-1519 (AET)  
(Consolidated)

CLASS ACTION

REPORT ON MARKET EFFICIENCY, LOSS CAUSATION, AND DAMAGES

STEVEN P. FEINSTEIN, PH.D., CFA

JUNE 6, 2011

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### **SCOPE OF PROJECT AND REPORT**

1. I was asked by Robbins Geller Rudman & Dowd LLP, counsel for the Plaintiffs, to determine whether or not the common stock of Pharmacia Corporation (“Pharmacia” or the “Company”) traded in an efficient market during the Class Period, 17 April 2000 to 5 August 2001. I was also asked to determine whether investors suffered losses as a result of the Defendants’ alleged misdeeds described in Plaintiffs’ Consolidated Complaint for Violation of the Federal Securities Laws, filed 27 October 2003 (“Complaint”). I was also asked to quantify damages sustained, if any, on a per share basis and to provide an estimate of aggregate damages.
2. Toward these ends, I analyzed the market for Pharmacia common stock, the price behavior of the stock, and the factors that are generally accepted to be indicative of market efficiency. I examined Company press releases, conference call transcripts, equity analyst reports, news articles, Company documents obtained through discovery, SEC filings, trading volume, FDA reviewer reports, the performance of the overall stock market, and the performance of Pharmacia’s peers, as well as other pertinent data and documents. Exhibit-1 lists the documents I reviewed and relied upon in the course of this engagement.
3. This report presents my methodology, findings, and conclusions.
4. I understand that expert discovery is ongoing in this case. I may revise my report as additional information becomes available and as I conduct further analyses.

### **CREDENTIALS**

5. I, Steven P. Feinstein, am an Associate Professor of Finance at Babson College, and the president of Crowninshield Financial Research, Inc., a financial economics consulting firm.
6. I hold a Ph.D. in Economics from Yale University, a Master of Philosophy degree in Economics from Yale University, a Master of Arts in Economics from Yale University, and a Bachelor of Arts degree in Economics from Pomona College. I also hold the Chartered Financial Analyst (“CFA”) designation, granted by the CFA Institute.
7. At Babson College I have taught undergraduate and MBA level courses in Valuation, Investments, Equity Analysis, Fixed Income Analysis, Financial Management, Risk Management, Capital Markets, and Quantitative Methods. I have also taught executive



courses on investments and corporate financial management for numerous corporations.

Other courses I have taught are listed in my curriculum vitae, which is attached as Exhibit-2.

8. At Babson College, I have held the Chair in Applied Investments and served as the Director of the Stephen D. Cutler Investment Management Center, a research and education center dedicated to the study and teaching of investments and capital markets.
9. Prior to my joining the faculty at Babson College, I taught finance at Boston University. Previously, I was an Economist at the Federal Reserve Bank of Atlanta where my primary responsibilities were to monitor financial markets, analyze proposed regulation, and advise the Bank President in preparation for his participation in meetings of the Federal Open Market Committee – the government body responsible for monetary policy in the United States.
10. I have published extensively in the field of finance. My finance articles have appeared in *The Journal of Forensic Economics*, *Atlanta Federal Reserve Bank Economic Review*, *Derivatives Quarterly*, *Derivatives Weekly*, *The Engineering Economist*, *The Journal of Risk*, *The American Bankruptcy Institute Journal*, *The Journal of Financial Planning*, *Risk Management*, and *Primus*. A recent article has been accepted for publication and is forthcoming in *Managerial Finance*. I am the author of *Finance and Accounting for Project Management*, published by the American Management Association. I wrote two chapters in the book *The Portable MBA in Finance and Accounting* – one on corporate financial planning and the other on risk management. I have presented research at the annual conventions of the American Finance Association, the Academy of Financial Services, the Multinational Finance Society, the Financial Management Association, and the International Conference on Applied Business Research. Co-authored papers of mine have been presented at the Eastern Finance Association meetings and the Midwestern Finance Association meetings.
11. I have been selected to review papers for numerous finance journals and conferences, and I have reviewed finance textbook manuscripts for Prentice-Hall, Elsevier, Blackwell, and Southwestern Publishing. I have been quoted on matters relating to finance and investments in *The Wall Street Journal*, *The Washington Post*, *The New York Times*, *The Financial Times*, *Bloomberg News*, and *The Boston Globe*, and my research relating to financial

analysis and valuation has been discussed in *The Wall Street Journal*, *Bond Buyer*, and *Grant's Municipal Bond Observer*.

12. I am a member of the American Finance Association, the Financial Management Association, the North American Case Research Association, the CFA Institute, and the Boston Security Analysts Society, where I have served as a member of the education committee and ethics subcommittee. I served on the Fixed Income Specialization Examination Committee of the CFA Institute.
13. The CFA designation is the premier credential for financial analysts, worldwide. In order to receive this credential, applicants must pass a series of three exams covering such topics as equity analysis, financial valuation, business analysis, quantitative methods, investment analysis, portfolio management, risk management, financial accounting, and ethical and professional standards. For over ten years I taught in the Boston University CFA Review Program and the Boston Security Analysts Society CFA Review Program – two of the leading review programs that prepared candidates for the CFA exams. In both of these programs I taught candidates at the most advanced level.
14. In addition to my teaching, research, CFA, and academic community responsibilities, I practice extensively as a financial consultant. Past and present clients include the United States Securities and Exchange Commission, the Internal Revenue Service, the Attorney General of the State of Illinois, and the National Association of Securities Dealers. As a financial consultant, I have conducted analyses and presented opinions related to market efficiency, artificial inflation, loss causation, and damages in over 50 securities cases. Exhibit-3 lists my prior testimony appearances over the past four years.
15. My firm is being compensated at a rate of \$675 per hour for my work on this matter, and my compensation is not contingent on my findings or on the outcome of this matter. I am the president and founder of the consulting firm Crowninshield Financial Research, which receives compensation for the work performed by analysts who assist me on this case.

## CONCLUSIONS

16. Pharmacia stock traded in an efficient market over the course of the Class Period.
17. Pharmacia common stock satisfied the *Cammer* and *Krogerman* factors, which were adopted and applied by the *DVI* Court, and which consistent with financial economic principles and empirical research indicate market efficiency.
18. Statistical tests prove that there was a cause and effect relationship between the release of new material information and movements in the Pharmacia stock price. This empirical result not only indicates market efficiency, but demonstrates the essence of market efficiency.
19. Over the course of the Class Period, the alleged misrepresentations and omissions caused the price of Pharmacia stock to be artificially inflated. This conclusion is based on an analysis of Company statements, FDA reviewer reports, analyst reports, news articles, and on event study analysis.
20. Event study analysis, which considered and accounted for potentially confounding information, proves that the alleged misrepresentations and omissions caused the price of Pharmacia stock to be artificially inflated. The corrective disclosures caused the inflation to dissipate, which in turn caused the stock price drop and investor losses.
21. As a result of the Defendants' misrepresentations and omissions, the market price of Pharmacia stock was artificially inflated by \$5.92 per share throughout most of the Class Period, and by amounts ranging up to \$5.92 as inflation dissipated between 6 February and 8 February 2001. No detectable inflation remained after 8 February 2001.
22. Any investor who purchased Pharmacia stock when the price was artificially inflated and held that stock beyond a corrective disclosure date suffered a loss that was caused by the alleged misrepresentations and omissions. The loss ranged up to \$5.92 per share, depending on the timing of the stock purchase and sale.
23. Aggregate damages estimated by a two-trader proportional trading model, incorporating conservative assumptions, and assuming the 90-day PSLRA "bounce-back" period begins on 8 February 2001, amount to \$1.38 billion, excluding prejudgment interest. When computed with the 90-day bounce-back period commencing on 5 August 2001, the last day of the Class Period, the estimate of aggregate damages is \$1.59 billion. The conservative nature of these estimates is confirmed by comparisons with the aggregate damage estimates

computed by a model based on institutional holdings. The institutional damage estimates were substantially higher than the estimates computed by the proportional trading model.

## **FACTUAL BACKGROUND**

### **About the Company**

24. Throughout the Class Period, Pharmacia was in the business of developing, manufacturing, and marketing pharmaceuticals.<sup>1</sup>
25. Pharmacia Corporation was the product of the 31 March 2000 merger (the “Merger”) of Pharmacia & Upjohn, Inc. (“PNU”) and the Monsanto Company (“Old Monsanto”). Old Monsanto was renamed Pharmacia Corporation and PNU became a subsidiary of the combined Company.<sup>2</sup> Shares of PNU were converted into 1.19 shares of the newly formed entity.<sup>3</sup> Pharmacia’s common stock began trading on the New York Stock Exchange (“NYSE”) on 4 April 2000, under the ticker symbol PHA.
26. On 18 October 2000, Pharmacia Corporation spun-off 14.7% (the “Spin-Off”) of the new Monsanto subsidiary (“New Monsanto”), through an initial public offering (“IPO”) of New Monsanto shares. New Monsanto comprised the Company’s chemicals and agricultural business. Later, on 13 August 2002, Pharmacia completed a spin-off of its remaining 85.3% stake in New Monsanto through a tax-free dividend.<sup>4</sup>
27. Excluding the revenue generated by New Monsanto, the Company produced operating revenue of \$12.7 billion in 2000 and \$13.8 billion in 2001.<sup>5</sup> Net earnings were \$717 million in 2000 and \$1.5 billion in 2001, excluding the earnings derived from New Monsanto.<sup>6</sup>
28. As of the close of trading on 14 April 2000, the trading day prior to the start of the Class Period, Pharmacia’s market capitalization (the aggregate value of all outstanding common shares) was \$66.3 billion,<sup>7</sup> according to share price data obtained from the Center for

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<sup>1</sup> Pharmacia Corporation Form 10-K405 for the Fiscal Year Ended 31 December 2001, filed 5 March 2002, p. 4.

<sup>2</sup> *Ibid.*, p. 3.

<sup>3</sup> Monsanto Company Form 8-K, filed 25 January 2000.

<sup>4</sup> “Pharmacia Completing Monsanto Spinoff Tuesday,” *Reuters News*, 13 August 2002; and Pharmacia Corporation Form 10-K405 for the Fiscal Year Ended 31 December 2001, filed 5 March 2002, p. 3.

<sup>5</sup> Pharmacia Corporation Form 10-K405 for the Fiscal Year Ended 31 December 2001, filed 5 March 2002, p. 46.

<sup>6</sup> *Ibid.*

<sup>7</sup> Shares outstanding data were obtained from the Company’s SEC filings. For the first 12 trading days of the Class Period, I used the 1,248.1 million shares reportedly outstanding as of the completion of the March 31 merger.

Research in Security Prices (“CRSP”).<sup>8</sup> The market capitalization climbed to a Class Period peak of \$78.7 billion on 29 December 2000. By 6 August 2001, the day following the end of the Class Period, the Company’s market capitalization had fallen to \$57.2 billion. The decline in market capitalization from the peak during the Class Period to the day after the Class Period was \$21.4 billion,<sup>9</sup> representing a loss of 27.2% of the Company’s equity value.

29. On 14 April 2000, the trading day prior to the start of the Class Period, Pharmacia’s common stock price was \$53.13 per share. The peak share price during the Class Period was \$61.00 per share on 29 December 2000. By 6 August 2001, the day after the Class Period, the stock price had fallen to \$44.00 per share. This drop represents a decline of 17.2% over the course of the Class Period and a decline of 27.9% from the Class Period high.
30. Pharmacia stock prices, dividends, trading volume, and logarithmic returns are shown in Exhibit-4.
31. After the Class Period, on 13 July 2002, Pharmacia entered into a definitive merger agreement with Pfizer. Upon completion of the transaction, Pharmacia shareholders received 1.4 shares of Pfizer stock for each share of Pharmacia.<sup>10</sup>

### **Background Information**

32. The drug Celebrex (celecoxib) is a painkiller of the type known as a selective COX-2 inhibitor. Developed for sufferers of arthritis, Celebrex was intended to be a safer alternative to traditional non-steroidal anti-inflammatory drugs (“NSAIDs”) such as ibuprofen, diclofenac, and aspirin, whose long-term use has been associated with ulcers and other gastrointestinal (“GI”) problems.
33. The COX-1 enzyme helps protect the GI system. Because traditional NSAIDs block both COX-1 and COX-2 enzymes non-selectively, they diminish this protection. As a selective COX-2 inhibitor, Celebrex was intended to preserve the COX-1 enzyme’s protection of the GI system while providing pain and inflammation relief comparable to that of traditional NSAIDs. Potentially free of the negative GI side effects, Celebrex was intended to offer a

<sup>8</sup> CRSP is the preeminent provider of historical stock market databases used in academic financial research.

<sup>9</sup> The slight arithmetic discrepancy is due to rounding.

<sup>10</sup> Pharmacia Corporation Form 10-K for the Fiscal Year Ended 31 December 2002, filed 25 March 2003, p. 3.

superior long-term treatment for patients suffering from osteoarthritis (“OA”), rheumatoid arthritis (“RA”), and other ailments.<sup>11</sup>

34. Celebrex was developed by Searle, the pharmaceuticals division of Old Monsanto. The drug was approved by the U.S. Food and Drug Administration (“FDA”) on 31 December 1998 to treat RA and OA.<sup>12</sup> It was launched in early 1999 and co-marketed with Pfizer. The launch was highly successful. Nearly 56,000 prescriptions were filled for Celebrex in its first three weeks on the market, and Celebrex sales totaled \$1.4 billion in 1999. At the time, Celebrex was the most successful drug launch ever.<sup>13</sup>
35. Celebrex quickly became Pharmacia’s largest revenue producer and was an important contributor to its revenue and earnings growth. Celebrex represented 20.7% and 22.5% of Pharmacia’s pharmaceuticals sales for the fiscal years 2000 and 2001, respectively.<sup>14</sup> In those same years, sales of Celebrex were 3.7 and 3.5 times greater, respectively, than sales of Pharmacia’s second best selling drug, Ambien.<sup>15</sup>
36. In spite of the drug’s potentially improved GI safety profile, the FDA required that, until Searle performed more studies, Celebrex carry a warning label about bleeding, ulcers, and stomach perforations.<sup>16</sup> This was similar to the label required for traditional NSAIDs.
37. To provide the FDA with sufficient data to potentially remove Celebrex’s GI warning label, Searle conducted the Celecoxib Long-Term Arthritis Safety Study (“CLASS”). The CLASS study was a double-blind outcomes trial involving approximately 8,000 arthritis patients, some of whom were given doses of Celebrex while control groups were given either ibuprofen or diclofenac, over a time span up to 15 months in length. The study was

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<sup>11</sup> “Executive Summary: Celebra Life Cycle Plan 1998-1999 Budget,” 21 June 1998, Exhibit-126 [DEFS 01380796].

<sup>12</sup> “DJBN Health-Care Report: FDA Clears Monsanto’s Arthritis Drug,” *Dow Jones Business News*, 31 December 1998.

<sup>13</sup> “Pain, Pain Go Away Is Celebrex – the New Arthritis Drug – All It’s Cracked Up To Be?” by Andrea Rock, *Money Magazine*, 1 April 1999, and “Chief Scientist Has Built His Reputation on Success,” by Adam Goodman, *St. Louis Post-Dispatch*, 26 December 1999.

<sup>14</sup> Pharmacia Corporation Form 10-K405 for the Fiscal Year Ended 31 December 2001, filed 5 March 2002, p. 32.

<sup>15</sup> *Ibid.*

<sup>16</sup> “Pain, Pain Go Away; Is Celebrex – the New Arthritis Drug – All It’s Cracked Up To Be?” by Andrea Rock, *Money Magazine*, 1 April 1999, and “Chief Scientist Has Built His Reputation On Success,” by Adam Goodman, *St. Louis Post-Dispatch*, 26 December 1999.

designed to assess the safety of Celebrex and compare the drug's safety with that of ibuprofen and diclofenac, two traditional and commonly used NSAIDs.<sup>17</sup>

38. When designing CLASS, the Company anticipated the study would achieve several beneficial objectives. Company planning materials indicated that regulatory objectives included facilitating a favorable label change that would differentiate Celebrex from traditional NSAIDs on the basis of GI safety.

“Far and away, the single largest item in the budget is the CLASS trials. These are large, GI event-based studies with the potential for major regulatory and commercial benefits.

Regulatory:

Such a study would:

- provide the basis for requesting a modification of the GI warning in the U.S. label in the event that that NSAID class warning is imposed on SCI labeling by FDA
- set a precedent for qualification of other compounds into the SCI Class
- be endorsed by the FDA Advisory Committee”

**“Executive Summary: Celebra Life Cycle Plan 1998-1999 Budget,” dated 21 June 1998, Exhibit-126, [DEFS 01380797].**

39. The same Company planning document indicated that the CLASS study was intended to produce commercial benefits, quantified as an approximately \$300 million increase in peak sales.

“Commercial:

Such a study would:

- provide a publication in a high quality journal
- provide pharmacoeconomic data required in markets like Canada and Australia
- health care resource utilization which is of importance to managed care organizations

An outcome study is in keeping with best practices of competitors like Merck

It is estimated that such a study could contribute ~\$300 million change in peak sales based on:

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<sup>17</sup> “Incidence of Clinically Significant UGI Adverse Events vs Diclofenac (Revision 1),” 26 October 1998, Exhibit-77 [DEFS 00064858 – 00064941], and “Incidence of Clinically Significant UGI Adverse Events vs Ibuprofen,” 18 August 1998, Exhibit-78 [DEFS 00064942 – DEFS 00065016].



- deletion of class warning
  - participants in outcome studies have higher prescribing practices”
- “Executive Summary: Celebra Life Cycle Plan 1998-1999 Budget,” dated 21 June 1998, Exhibit-126, [DEFS 01380798].

### **Timeline of Important Events**

40. Among the important events relevant to an understanding of the Company’s experience over the course of the Class Period and of the Plaintiffs’ allegations are the following.

#### **17 April 2000: Pharmacia Announces the CLASS Results**

41. A joint press release issued by Pharmacia and Pfizer on 17 April 2000 announced the results of CLASS. The statement used glowing terms to characterize CLASS as “a landmark study,” “groundbreaking,” and a “rigorous outcomes trial [that] set the bar higher than any previous study of its kind.”<sup>18</sup>
42. Celebrex’s performance in the study was also described in exceptionally positive terms.

“In a landmark study to assess the overall long-term safety of the COX-2 specific inhibitor Celebrex(R) (celecoxib capsules), arthritis patients taking four times the recommended osteoarthritis (OA) dose of the drug experienced fewer symptomatic gastrointestinal (GI) ulcers and ulcer complications than patients taking ibuprofen and diclofenac – a difference that was statistically significant based on a combined analysis of Celebrex versus these two traditional nonsteroidal anti-inflammatory drugs (NSAIDs).

...

The study, funded by Searle and Pfizer Inc, found that Celebrex patients experienced significantly fewer symptomatic GI ulcers and ulcer complications compared with ibuprofen or diclofenac. Celebrex was also associated with numerically fewer ulcer complications than the NSAID comparators among all patients, and 64 percent fewer of these serious events among non-aspirin users – a statistically significant difference.”  
“New Findings Presented on Celebrex(R) Safety and Tolerability from Long-Term Outcomes Study of 8,000 Arthritis Patients,” Pharmacia and Pfizer joint press release, *PR Newswire*, 17 April 2000.

43. According to the press release, Celebrex proved superior with respect to the frequency of ulcer complications when patients taking aspirin were excluded. Moreover, according to

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<sup>18</sup> “New Findings Presented on Celebrex(R) Safety and Tolerability From Long-Term Outcomes Study of 8,000 Arthritis Patients,” Pharmacia and Pfizer joint press release, *PR Newswire*, 17 April 2000.



the press release, when grouping ulcer complications together with symptomatic ulcers, Celebrex proved statistically superior to ibuprofen or diclofenac.

44. The press release quoted medical researchers validating the study, its results, and the implication that CLASS proved Celebrex to be safer with respect to GI effects.

“‘No previous study has examined such a broad range of GI side effects – which encompass events ranging from serious and often devastating GI ulcers and ulcer complications, to silent but medically important damage to the lining of the intestine, to symptoms like abdominal pain,’ said Lee S. Simon, M.D., associate professor of medicine, Harvard Medical School. ‘We’ve known the serious risks of traditional NSAIDs for some time, but these long-term findings show that patients taking Celebrex, in contrast to those on ibuprofen or diclofenac, experienced fewer treatment-related side effects in a number of important areas. These side effects often limit patients’ ability to maintain their therapy and get the arthritis pain relief they require.’”

...

“‘This rigorous outcomes trial set the bar higher than any previous study of its kind. It included a large number of patients who received four times the recommended OA dose of Celebrex for up to 13 months. It also compared Celebrex with commonly used traditional NSAIDs – ibuprofen, one of the most well tolerated; and diclofenac, extensively used throughout the world,’ said Fred Silverstein, M.D., chairperson of the study’s external review board. ‘Even at these very high doses, Celebrex showed sustained safety and tolerability in organ systems often affected by NSAIDs. As such, these are compelling findings for physicians to consider when treating arthritis patients.’”

**“New Findings Presented on Celebrex(R) Safety and Tolerability From Long-Term Outcomes Study of 8,000 Arthritis Patients,” Pharmacia and Pfizer joint press release, *PR Newswire*, 17 April 2000.**

45. The press release did not disclose that the entire study results were far less favorable to Celebrex than the publicly reported six-month results, as 6 of the 7 complicated ulcers occurring after the first six months of the CLASS trial were suffered by patients being treated with Celebrex, the reported GI comparisons worsened after six months, and the statistically significant benefit for Celebrex users not taking aspirin that Defendants reported based upon six months of data for complicated ulcers did not hold for the entire study period. Furthermore, Celebrex failed to establish any statistically significant difference with diclofenac on any of the GI endpoints considered, and diclofenac was

actually numerically superior to Celebrex on one of the two co-primary endpoints of the study.<sup>19</sup>

46. Morgan Stanley discussed the results of CLASS in an analyst report titled “Positive Results of Celebrex CLASS Trial Released,” published the day following the joint press release. The Morgan Stanley analysts reported exactly what the release had represented, *i.e.*, that Celebrex patients experienced fewer symptomatic ulcers and ulcer complications compared to the NSAID treatment groups, and that the study had successfully differentiated the GI safety profile of Celebrex from that of the traditional NSAIDs.

**“PHA and PFE announced positive results of the CLASS trial**

In most respects, the study served its purpose of differentiating the long-term safety profile of Celebrex from NSAIDs.

**Celebrex patients experienced fewer symptomatic ulcers**

and ulcer complications than patients taking the comparator NSAIDs, ibuprofen and diclofenac.”

**“Positive Results of Celebrex CLASS Trial Released,” by Jami Rubin, Mark Wiltamuth and Nancy Yu, Morgan Stanley Dean Witter, analyst report, 18 April 2000, p. 1 (emphasis in original).**

47. Notwithstanding the fact that the CLASS trial “fell short” of its primary endpoint – establishing statistically significantly fewer ulcer complications among all patients taking Celebrex – the Morgan Stanley analysts commented that they had “anticipated the study to corroborate” the GI safety profile of Celebrex. For this reason, they would not change their sales forecasts for the drug.

“We are making no change to our forecasts, as we had anticipated the study to corroborate the strong safety profile of the product.”

**“Positive Results of Celebrex CLASS Trial Released,” by Jami Rubin, Mark Wiltamuth and Nancy Yu, Morgan Stanley, analyst report, 18 April 2000.**

48. The analysts concluded that, on the basis of the result achieved when grouping ulcer complications with symptomatic ulcers and on the basis of the result achieved among non-aspirin patients, the study “served its purpose of differentiating the long-term safety profile of Celebrex from NSAIDs.”

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<sup>19</sup> “New Findings Presented on Celebrex(R) Safety and Tolerability From Long-Term Outcomes Study of 8,000 Arthritis Patients,” Pharmacia and Pfizer joint press release, 17 April 2000, Exhibit-67 [DEFS 00404977 – DEFS 00404980]; and Affidavit of Howard R. Philips, 18 October 2010, Attachments A – C.

49. From the close of trading on Friday, 14 April 2000, to the close of trading on Wednesday, 19 April 2000, the price of Pharmacia stock rose \$6.62 per share, from \$53.13 to \$59.75 per share, an increase of 12.5%.

25 April 2000: Q1 2000 Earnings and Conference Call

50. On 25 April 2000, Pharmacia announced Q1 2000 financial results and held a conference call with investors. During the call, Company executives reiterated the CLASS study results and their implications. Referring to CLASS, Pharmacia CEO Fred Hassan claimed that “new data” showed Celebrex’s “exceptional safety profile.”
51. Further, Executive VP Alan Heller touted the results of the “long-term” study and Celebrex’s “broad safety profile” when compared against traditional NSAIDs, including diclofenac.

“[Alan Heller, Head of Searle Units, Pharmacia Corporation:] The top line take-away is that our landmark long-term arthritis study provides compelling evidence of the broad safety profile of Celebrex across a full spectrum of GI measures and in major organ systems versus the traditional NSAID comparators ibuprofen and diclofenac.

...

When we focus only [on] the most serious GI events, meaning ulcer complications, which include perforations, gastric obstructions and GI bleeds, among all patients including those using low-dose aspirin, Celebrex resulted in 52% fewer ulcer complications, a finding that was just under statistical significance. Among non-aspirin users, the difference was 65%, which was statistically significant.”

**“Pharmacia Corporation First Quarter Earnings Release Conference Call,” 25 April 2000, Exhibit 336, [DEFS 01221352].**

52. Investors and analysts were still not made aware of the facts set forth above in paragraph 45. They were not informed that the results for the entire CLASS study were far less favorable for Celebrex than what Defendants represented.
53. Responding to Pharmacia’s Q1 2000 financial results, analyst reports were positive about the impact that the CLASS study would have on the Celebrex franchise. They anticipated that the new research would enable Pharmacia to remove the GI warning from the Celebrex label. Among other benefits, the label change would enable more widespread usage and reimbursement approval by managed care providers.

“Celebrex sales were impressive, although somewhat lower than we had expected. However, we continue to believe that Celebrex will show impressive growth during the coming quarters, fuelled by new research data.”

**“Ready for a Pick-Up Later This Year!” by Peter Sellei and Kristofer Liljeberg-Svensson, Carnegie, analyst report, 25 April 2000, p. 1.**

“PHA will expand upon the recently announced GI safety data with a more complete presentation at the Digestive Disease Week Conference May 21-24. This data is expected to show much lower incidence of GI complications than traditional NSAID’s, and an FDA filing this quarter could remove the NSAID warning label as soon as late 2000. This occurrence would open the door for more widespread usage at managed care facilities.”

**“Celebrex Poised to Bounce; AG Weakness Less Important,” ABN AMRO, analyst report, 25 April 2000, p. 2.**

“The ‘next big thing’ in the Celebrex story should take place around mid-year, when PHA and PFE are expected to submit a supplemental NDA (sNDA) with the results of their outcomes trial (the CLASS trial). Positive results of the trial were recently presented, demonstrating that OA and RA patients taking four times the recommended OA dose of the drug (800 mg/day) experienced fewer symptomatic gastrointestinal ulcers and ulcer complications than patients taking the other two drugs. The objective in submitting these trials to the FDA is to convince the agency to revise the label on Celebrex, which currently includes the standard NSAID warning. Removal, or even significant revision, of this warning would likely have a major positive impact on reimbursement practices and sales of the product.”

**“Ag Off to a Slow Start, but 2000 EPS In Tact,” by Jami Rubin, Mark Wiltamuth and Nancy Yu, Morgan Stanley Dean Witter, analyst report, 26 April 2000, p. 3.**

“We believe the long-term safety data generated by the CLASS (Celebrex) and VIGOR (Merck’s Vioxx) trials will re-accelerate the coxibs’ penetration of the NSAID market by removing the NSAID side effects warning label.”

**“Ag. Franchise in a Q1 Drought: Pharma Will Pick Up the Slack,” by Ian Sanderson *et al.*, SG Cowen, analyst report, 26 April 2000, p. 3.**

22-23 May 2000: Presentation of CLASS Results at the Digestive Disease Week Conference and Press Release

54. On the evening of 22 May 2000, at the Digestive Disease Week conference, Defendants once again presented findings drawn from the CLASS trial data.

55. The next day, Pharmacia and Pfizer issued a joint press release reiterating many of the initially reported findings.

“Under the real-world conditions of the study, significant decreases in the use of medical resources were shown in the Celebrex group versus the other NSAIDs studied. ... This amounted to 25 percent fewer office visits and complex work-ups for patients taking Celebrex.”

**“Findings from Celebrex(R) Safety Study Show Traditional NSAID Comparators Can Cause Serious GI Complications Within First Few Days of Treatment, No Increased Risk of GI Complications Observed for H. Pylori Positive Patients on Celebrex,” Pharmacia and Pfizer joint press release, *PR Newswire*, 23 May 2000.**

“Among non-aspirin users, patients on Celebrex taking four times the recommended dose for OA experienced significantly fewer ulcer complications compared with ibuprofen and diclofenac.”

*Ibid.*

56. In the press release Defendants labeled aspirin as an “independent risk factor for ulcers” and stated that removing aspirin patients from the analysis “offers a clearer picture” of Celebrex’s GI safety profile.

“Patients who needed aspirin were allowed to participate in this study since a large number of patients with arthritis take low-dose aspirin for cardioprotection, as did one-in-five patients in this study. Excluding aspirin patients from the analysis, however, offers a clearer picture of the impact of Celebrex on GI safety since aspirin is an independent risk factor for GI complications. These patients experienced three-fold fewer (64 percent) ulcer complications, a statistically significant difference from the NSAID comparators. When patients taking aspirin for cardioprotection were added to the analysis, those on Celebrex experienced two-fold fewer ulcer complications versus the traditional NSAID comparators, narrowly missing statistical significance.”

**“Findings from Celebrex(R) Safety Study Show Traditional NSAID Comparators Can Cause Serious GI Complications Within First Few Days of Treatment; No Increased Risk of GI Complications Observed for H. Pylori Positive Patients on Celebrex,” Pharmacia and Pfizer joint press release, *PR Newswire*, 23 May 2000.**

57. Investors were still left unaware of the facts described above in paragraph 45.
58. Morgan Stanley analysts reported on the conference presentation. It appears they were under the impression that the data Defendants presented at the conference constituted all of the data generated by the CLASS study.

“The full data from the VIGOR and CLASS clinical outcomes studies were presented this week at the Digestive Disease Week (DDW) conference in San Diego.

Both studies successfully differentiated the long-term GI safety profile of the COX-2 inhibitors, Vioxx and Celebrex, relative to traditional NSAIDs.”

**“Positive Clinical Outcomes Studies Presented at DDW,” by Jami Rubin, Mark Wiltamuth and Nancy Yu, Morgan Stanley Dean Witter, analyst report, 25 May 2000, p. 1.**

59. These analysts apparently believed the data confirmed the superior GI safety of Celebrex. They anticipated that the positive study results would be included on the product label, and that submitting the data to the FDA could ultimately result in removal of the GI warning.

“In our opinion, the data presented this week at the Digestive Disease Week conference serve to further validate the COX-2 inhibitors’ differentiated safety profile in the GI tract. Both the VIGOR trial for Vioxx and the CLASS trial for Celebrex produced robust data documenting a significant reduction in symptomatic ulcers and ulcer complications relative to commonly prescribed NSAIDs. Though there were some differences in study designs and the results of the trials, neither product emerges as clearly superior to the other, in our opinion. At a minimum, we expect the labels of both products to be augmented to include this exciting new safety data, which should prove valuable in bolstering the marketing messages of both agents. Obviously, the ultimate goal of submitting these data is removal of the GI warning which appears in both products’ labels (as well as those of all traditional NSAIDs).”

**“Positive Clinical Outcomes Studies Presented at DDW,” by Jami Rubin, Mark Wiltamuth and Nancy Yu, Morgan Stanley Dean Witter, analyst report, 25 May 2000, pp. 5-6.**

60. Internal Pfizer communications acknowledged that Defendants’ representations related to the CLASS results and the GI safety profile of Celebrex had been accepted. In an email referring to the 23 May 2000 press release, Samuel Zwillich wrote:

“They swallowed our story, hook, line and sinker...”

**“CBX-0082360\_RE: Good News on Celebrex,” Company email from Samuel H. Zwillich to Mona M. Wahba, dated 23 May 2000, Exhibit-214, [DEFS 00728751] (ellipses in original).**

13 September 2000: JAMA Publishes Article Authored by Pharmacia Employees and Consultants

61. From the early planning stages, one stated goal of the CLASS study was to “provide a publication in a high quality journal.”<sup>20</sup> Defendants considered that such an article publicizing the positive GI safety profile of Celebrex would be commercially valuable.<sup>21</sup>
62. On 13 September 2000, an article about the CLASS study, written by Pharmacia employees and paid consultants, was published in the *Journal of the American Medical Association (JAMA)*.
63. The article reported clinical results only from the first six months of the study. It concluded, based only on the 6-month data, that Celebrex was safer than traditional NSAIDs.

**“Participants:** A total of 8059 patients ( $\geq 18$  years old) with osteoarthritis (OA) or rheumatoid arthritis (RA) were enrolled in the study, and 7968 received at least 1 dose of study drug. A total of 4573 patients (57%) received treatment for 6 months.

...

**Main Outcome Measures:** Incidence of prospectively defined symptomatic upper GI ulcers and ulcer complications (bleeding, perforation, and obstruction) and other adverse effects during the 6-month treatment period.

...

Time-to-event analyses of upper GI ulcer complications alone or combined with symptomatic ulcers were performed based on cumulative event rates (symptomatic ulcers and/or ulcer complications) for the 6-month study period and are expressed as annualized incidence rates (number of events per 100 patient-years of exposure or percentage).

...

The incidences of treatment-emergent adverse effects or clinical laboratory changes in the different treatment groups during the 6 months were compared using the Fisher exact test.

...

[O]ur results demonstrate that celecoxib, at a dosage 2- to 4-fold greater than the maximum therapeutic dosages and those approved for labeling for RA and OA, is associated with a lower rate of upper GI toxic effects

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<sup>20</sup> “Executive Summary: Celebra Life Cycle Plan 1998-1999 Budget,” 21 June 1998, Exhibit-126, [DEFS 01380798].

<sup>21</sup> *Ibid.*



compared with standard therapeutic dosages of NSAIDs. This finding supports the COX-2 hypothesis that COX-2-specific agents exhibit decreased GI toxic effects.”

**“Gastrointestinal Toxicity with Celecoxib vs Nonsteroidal Anti-inflammatory Drugs for Osteoarthritis and Rheumatoid Arthritis; the CLASS Study: A Randomized Controlled Trial,” by Fred E. Silverstein, M.D., et al., *Journal of the American Medical Association*, 13 September 2000.**

64. The *JAMA* article stated that the main outcome measure for the CLASS study was the incidence of, collectively, ulcer complications, symptomatic ulcers, and other adverse effects. The article reported that on this basis Celebrex proved superior to the comparator NSAIDs, statistically significantly so. The article also reported that when the patients taking aspirin were excluded, Celebrex “was associated with a significantly lower incidence of symptomatic ulcers and/or ulcer complications compared with NSAIDs.”
65. The same *JAMA* issue included an editorial written by medical expert M. Michael Wolfe, a gastroenterologist at Boston University. Based on the findings reported in the article, Wolfe commented favorably on the CLASS study and Celebrex as a treatment option. The editorial described CLASS as “a 6-month randomized, double-blind, controlled trial.”<sup>22</sup>
66. On 13 September 2000, the date the publication appeared, Defendants issued a press release drawing attention to the *JAMA* article, the editorial, and the study findings as presented in the *JAMA* article.<sup>23</sup>
67. Neither the article, nor the editorial, nor the press release made investors aware of the facts described above in paragraph 45.
68. The press reported on the publication of the *JAMA* article and its finding that Celebrex was found to be safer than traditional NSAIDs.

“For the first time, a major medical study showed that the hot-selling arthritis drug Celebrex is associated with less clinically significant gastrointestinal bleeding and fewer ulcers than are older arthritis drugs.”  
**“Gastrointestinal Benefit Cited for Celebrex,” by Thomas M. Burton, *Wall Street Journal*, 13 September 2000.**

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<sup>22</sup> “COX-2-Selective NSAIDs: New and Improved?” by David R. Lichtenstein and M. Michael Wolfe, *Journal of the American Medical Association*, 13 September 2000, Exhibit-4, [WOLFE 00001].

<sup>23</sup> “JAMA Study Shows Arthritis Medication Causes Fewer Gastrointestinal Problems than Traditional Drugs,” Pharmacia, Pfizer, and the University of Illinois at Chicago College of Medicine press release, *PR Newswire*, 12 September 2000.



6-7 February 2001: FDA Posting of Review Reports and Advisory Committee Meeting

69. On or about 6 February 2001, prior to a meeting of the FDA's Arthritis Advisory Committee, the reports written by FDA reviewers that contained and analyzed CLASS data for the entire study were posted on the FDA's website. The postings included a 22-page "Statistical Reviewer Briefing Document for the Advisory Committee," a 93-page "Medical Officer's Gastroenterology Advisory Committee Briefing Document," a 100-page "Medical Officer Review,"<sup>24</sup> and a 103-page "Sponsor Briefing Document."<sup>25</sup>
70. While Defendants' earlier press releases, conference call statements, and conference presentations touted clinical results drawn from only the first six months of the CLASS study, and the *JAMA* article was similarly restricted to the first six months of the CLASS study, the FDA committee reviewed the entire approximately 13 months of CLASS data.
71. Late in the afternoon on 7 February 2001, the Advisory Committee released its conclusion that based on the full data set there was no significant GI safety advantage between the traditional NSAIDs and Celebrex. As a result, the Committee did not recommend that the FDA approve the label change Defendants sought.

"Scientific studies do not show that Pharmacia Corp.'s blockbuster arthritis treatment Celebrex is safer than traditional painkillers, a U.S. advisory panel said on Wednesday.

A Food and Drug Administration advisory committee said a study by Pharmacia unit Searle did not find that Celebrex caused fewer stomach-related side effects than other pain remedies known as NSAIDs, or nonsteroidal anti-inflammatory drugs.

'The consensus of the panel is there is no clinically meaningful safety advantage in upper (gastrointestinal) safety,' said acting panel Chairman E. Nigel Harris."

**"No safety edge seen for Pharmacia's Celebrex-panel," *Reuters News*, 7 February 2001.**

72. Commentary from the medical community and the financial media continued after the close of trading on 7 February 2001 and carried over to 8 February 2001.

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<sup>24</sup> Affidavit of Howard R. Philips, 18 October 2010, Attachments A – C, and "UPDATE 1-Safety of Popular Arthritis Drugs Under US Review," by Lisa Richwine, *Reuters News*, 6 February 2001.

<sup>25</sup> "CLASS Advisory Committee; Briefing Document," G.D. Searle & Co., dated 7 February 2001.

“‘A seemingly magical bullet seems to have self-destructed ... It appears to have been grossly exaggerated and oversold,’ said Dr. Sidney Wolfe, head of the Health Research Group at consumer group Public Citizen.”

**“Update 2-US Panel Sees No Safety Edge for Celebrex,” by Lisa Richwine, *Reuters News*, 7 February 2001.**

“Celebrex shows a benefit in reducing ‘symptomatic ulcers’ vs other NSAIDs. Overall, Celebrex may be safer than the ‘old NSAIDs’, but the CLASS trial (at a dose 2-4x normal) did not convince the FDA committee.”

**“PHA: FDA Reviews Celebrex & Vioxx Safety Data,” by Mark Striker and George Grofik, *Salomon Smith Barney*, analyst report, 7 February 2001, p. 1.**

“FDA Panel Rejects Label Change. An FDA Advisory Committee rejected the notion that Celebrex, a COX-2 inhibitor, has a better safety profile NSAIDs. PHA shares sold off (3+%) based on concerns that Celebrex’s growth will stagnate without a label change.”

**“CLASS Flunks Out,” by Mara Goldstein, Steven Gerber, M.D., and Adam Sohn, *CIBC*, analyst report, 8 February 2001, p. 1.**

73. The new information provided to the market was complex, voluminous, and irregular in that it ran contrary to prior representations and that its time of release was not scheduled with precision. Consequently, it took some time for the market to process the new information.
74. With sufficient time, on account of acquiring and processing the reports posted on the FDA website, on account of statements from the FDA Advisory Committee, and facilitated by media reports and analyst commentary, the market learned what had previously been concealed. In particular, the market learned that the entire study results were far less favorable to Celebrex than the publicly reported six-month results, as 6 of the 7 complicated ulcers occurring after the first six months of the CLASS trial were suffered by patients being treated with Celebrex, the reported GI comparisons worsened after six months, and the statistically significant benefit for Celebrex users not taking aspirin that Defendants reported based upon six months of data for complicated ulcers did not hold for the entire study period. The market also learned that Celebrex failed to establish any statistically significant difference with diclofenac on any of the GI endpoints considered,

and that diclofenac was actually numerically superior to Celebrex on one of the two co-primary endpoints of the study.<sup>26</sup>

75. From the close of trading on Monday, 5 February 2001, to the close on Thursday, 8 February 2001, the price of Pharmacia stock fell \$5.28 per share, from \$58.28 to \$53.00 per share, a 9.1% decline. As shown below, this is a statistically significant three-day stock price decline. Moreover, the single-day stock price declines on February 7<sup>th</sup> and 8<sup>th</sup> were statistically significant individually.

5 August 2001: *Washington Post* Exposé States Defendants Misled *JAMA* Editors and the Public

76. In a 5 August 2001 article, the *Washington Post* revealed that, at the time Defendants touted the GI safety purportedly demonstrated by the CLASS study, they actually possessed the full set of data indicating that Celebrex held no such advantage after the first six months.
77. M. Michael Wolfe, the gastroenterology expert whose favorable editorial about Celebrex had accompanied the *JAMA* article, was quoted as saying he was “flabbergasted” to learn that the study had lasted a year rather than just six months. While the six-month data appeared to show that Celebrex’s GI safety profile was superior, most of the ulcer complications developed by CLASS patients in the latter half of the study were in Celebrex patients, eliminating the purported GI safety advantage.

“The study – already completed at the time he wrote the editorial – had lasted a year, not six months as he had thought, Wolfe learned. Almost all of the ulcer complications that occurred during the second half of the study were in Celebrex users. When all of the data were considered, most of Celebrex’s apparent safety advantage disappeared.”

**“Missing Data on Celebrex; Full Study Altered Picture of Drug,” by Susan Okie, *Washington Post*, 5 August 2001.**

78. Dr. Wolfe expressed that he had been misled, and the editor of *JAMA* stated that Defendants’ actions had perhaps broken a level of trust.

“‘I am furious. ... I wrote the editorial. I looked like a fool,’ said Wolfe, a Boston University gastroenterologist. ‘But ... all I had available to me was the data presented in the article.’

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<sup>26</sup> Affidavit of Howard R. Philips, 18 October 2010, Attachments A – C.

*JAMA*'s editor, Catherine D. DeAngelis, said the journal's editors were not informed about the missing data. 'I am disheartened to hear that they had those data at the time that they submitted [the manuscript] to us,' she said. 'We are functioning on a level of trust that was, perhaps, broken.'" **"Missing Data on Celebrex; Full Study Altered Picture of Drug,"** by Susan Okie, *Washington Post*, 5 August 2001.

79. The *Washington Post* exposé noted that the *JAMA* article, though apparently the result of deception, was commercially valuable to Pharmacia.

"Meanwhile, the *JAMA* article and editorial have likely contributed to Celebrex's huge sales. 'When the *JAMA* article comes out and confirms the hype, that probably has more impact than our labeling does,' said Robert J. Temple, director of medical policy at the FDA's Center for Drug Evaluation and Research."

**"Missing Data on Celebrex; Full Study Altered Picture of Drug,"** by Susan Okie, *Washington Post*, 5 August 2001.

Post-Class Period: Confirmation of Deception

80. On 1 June 2002, after the end of the Class Period, the *British Medical Journal* published an article which, among other things, raised concerns about the conclusions and representations made in the 13 September 2000 *JAMA* article that touted the results of the CLASS study and the GI safety of Celebrex. Moreover, the authors believed that the "misleading" conclusions and "flawed findings" published in *JAMA*, along with the subsequent distribution of the article to physicians, coincided with approximately \$500 million of increased sales of Celebrex.

"[T]he flawed findings published in the original article appear to be widely distributed and believed. About 30,000 reprints of CLASS were bought from the publisher (W Bartolotta, personal communication), and a recent search of the Science Citation Index yielded 169 articles citing it, more than 10 times as many citations as for any other article published in the same issue. This wide distribution and citation has coincided with the sales of celecoxib increasing from \$2,623m in 2000 to \$3,114m in 2001.

Publishing and distributing overoptimistic short term data using post hoc changes to the protocol, while omitting disappointing long term data of two trials, which involved large numbers of volunteers, is misleading."

**"Are Selective COX 2 Inhibitors Superior to Traditional Non Steroidal Anti-Inflammatory Drugs?"** by Peter Juni, Anne W S Rutjes, and Paul A Dieppe, *British Medical Journal*, 1 June 2002, 324, 7349, p. 1288.

81. According to an article titled, “The Credibility Gap in Drug Research,” published in *BusinessWeek* on June 24, 2002, *JAMA* deputy editor Drummond Rennie stated that he was misled by Pharmacia executives into publishing incomplete and contradicted results.

“*The British Medical Journal* says the article was misleading because it omitted data that found no safety benefit for Celebrex. (The additional data were later made public at a Food & Drug Administration advisory committee meeting.)

G. Steven Geis, Pharmacia’s vice-president for research, says information was omitted only because it was not reliable. On June 7, however, the FDA decided, using all the data, that the study ‘did not show a safety advantage in upper gastrointestinal events for Celebrex.’

...

[Drummond Rennie, deputy editor at *JAMA*] is still rankled, however, by *JAMA*’s publication of the Celebrex study. The study’s authors, including Pharmacia, ‘were not open with us,’ he says. ‘They signed letters saying the studies have all the relevant stuff,’ but ‘they had contradictory results when they sent us this paper, and they should have revealed them to us. And they didn’t.’”

“**The Credibility Gap in Drug Research,” by Paul Raeburn, *BusinessWeek*, 24 June 2002.**

### **EFFICIENT MARKET DEFINED**

82. In a March 2011 decision in the case *In DVI, Inc.* No. 08-8033, 2011 U.S. App. LEXIS 6302 (3<sup>rd</sup> Cir. March 29, 2011) (“*DVI*”), the Third Circuit Court of Appeals (“*DVI* Court”) reviewed and affirmed the determination made by the District court that the common stock and senior notes of DVI, Inc. traded in efficient markets.
83. For the definition of an efficient market, the *DVI* Court cited the Supreme Court’s *Basic Inc. v. Levinson* 485 U.S. 224 (1988), decision.

“‘The fraud on the market theory is based on the hypothesis that, in an open and developed securities market, the price of a company’s stock is determined by the available material information regarding the company and its business. ... Misleading statements will therefore defraud purchasers of stock even if the purchasers do not directly rely on the misstatements. ...’ This hypothesis is known as the efficient capital market hypothesis.”

***DVI*, 2011 U.S. App. LEXIS 6302, at \*10-\*13 (quoting *Basic*, 485 U.S. at 241-42).**

84. This definition adopted by the *DVI* Court is consistent with the definition generally accepted by the academic finance community.
85. The *DVI* Court upheld the District court's analysis of market efficiency, which relied in large part on the factors identified in *Cammer v. Bloom* 711 F. Supp. 1264 (D.N.J. 1989), a case which is frequently cited as a legal authority for establishing the meaning of market efficiency in securities cases.

“The District court considered efficiency factors set forth in *Cammer v. Bloom*, 711 F. Supp. 1264, 1286-87 (D.N.J. 1989) ...”  
***DVI*, 2011 U.S. App. LEXIS 6302, \*17 n. 14.**

86. The definition of market efficiency set forth by Judge Alfred J. Lechner, Jr. in the *Cammer* decision in the New Jersey District Court (“*Cammer* Court”) is similarly consistent with the definition generally accepted by the academic finance community:

“As relevant here, courts have permitted a rebuttable presumption of reliance in the case of securities traded in ‘efficient markets’ (*i.e.*, markets which are so active and followed that material information disclosed by a company is expected to be reflected in the stock price).”  
***Cammer*, 711 F. Supp. at 1273 n. 11 (parentheses as in original).**

87. Judge Lechner in the *Cammer* case cited the definitions offered by commentators Alan R. Bromberg and Lewis D. Lowenfels, and by finance professor Eugene Fama:

“An efficient market is one which rapidly reflects new information in price.”  
***Cammer*, 711 F. Supp. at 1276 n. 17 (quoting Bromberg and Lowenfels, *Securities Fraud and Commodities Fraud*, §8.6, 1988).**

“A market in which prices always ‘fully reflect’ available information is called ‘efficient.’”  
***Cammer*, 711 F. Supp. at 1280 n. 25 (quoting “Efficient Capital Markets: A Review of Theory and Empirical Work,” by Eugene F. Fama, *Journal of Finance*, 1970).**

88. The definitions are consistent with one another. An efficient market, as defined by the *DVI* Court, the *Cammer* Court, The Supreme Court in *Basic*, Bromberg and Lowenfels, and Fama, is a market in which available information is rapidly incorporated into the prices of securities such that the trading price reflects all available information.

89. Market efficiency is relevant to a securities case as it addresses the question of whether or not false information (be it in the form of an alleged misrepresentation or an omission) would have impacted the prices at which investors bought and sold.

The *Cammer* Factors

90. The *Cammer* opinion lays out five factors that would suggest the market for a security is efficient. As elaborated below, economic rationales support each factor as an indicator of market efficiency. The five factors are: 1) trading volume, 2) coverage by securities analysts, 3) number of market makers, 4) eligibility for S-3 registration, and 5) empirical evidence that the security price reacts to material information. These factors were adopted by the District court in the *DVI* case for evaluating the efficiency of the market for *DVI* securities. Their use was deemed by the *DVI* Court to be proper:

“The District court considered efficiency factors set forth in *Cammer v. Bloom*: (1) the average weekly trading volume; (2) the number of security analysts following and reporting on the security; (3) the extent to which market makers traded the security; (4) the issuer’s eligibility to file an SEC registration Form S-3; and (5) the cause-and-effect relationship between material disclosures and changes in the security’s price.”  
*DVI*, 2011 U.S. App. LEXIS 6302, at \* 21 n. 14 (internal citations omitted).

“We have noted the *Cammer* factors may be instructive depending on the circumstances. Many of our sister circuits have also approved of their use.”  
*DVI*, 2011 U.S. App. LEXIS 6302, at \*24 n. 16.

91. Empirical research has confirmed that volume, number of market makers, and analyst coverage are indicative of market efficiency:

“Consistent with the efficiency indicators used recently by the courts, the inefficient firms have lower mean trading volume, fewer market makers, lower analyst following, and lower institutional ownership (number and percentage) than efficient firms.”  
“The Fraud-on-the-Market Theory and the Indicators of Common Stocks’ Efficiency,” by Brad M. Barber, Paul A. Griffin, and Baruch Lev, *Journal of Corporation Law*, 1994, p. 302.

92. Barber, Griffin, and Lev [1994] did not test S-3 registration eligibility as an indicator of market efficiency, but it is noteworthy that the S-3 eligibility criteria include a minimum



market capitalization requirement, and large firm size is correlated with high institutional ownership, a factor which Barber, *et al.* did find to be indicative of market efficiency. With respect to the empirical factor, Barber, *et al.* used empirical tests as the standard for market efficiency by which to judge the significance of the other variables. Consequently, they acknowledge the importance of the empirical factor.

93. Consistent with financial economic theory and empirical research, the language used by the *Cammer* Court describes the factors not as five ***necessary*** factors, but rather as indicative of the degree to which the security market is expected to be efficient:

“There are several different characteristics pertaining to the markets for individual stocks which are probative of the degree to which the purchase price of a stock should reflect material company disclosures.”  
*Cammer*, 711 F. Supp. at 1283.

94. In fact, the way the five factors are described in the *Cammer* opinion suggests that these five conditions are more akin to sufficient conditions individually, rather than necessary conditions collectively – again, consistent with economic theory. The *Cammer* opinion describes the nature of the five factors as follows:

“There are several types of facts which, if alleged, might give rise to an inference that Coated Sales traded in an efficient market. It is useful to set forth an explanation of how the existence of such facts would cause the understanding that disclosed company information (or misinformation) would be reflected in the company’s stock price, the underpinning of the fraud on the market theory. *Peil, supra*, 806 F.2d at 1160.”  
*Cammer*, 711 F. Supp. at 1285-86 (footnote omitted).

“First, plaintiffs could have alleged there existed an average weekly trading volume during the class period in excess of a certain number of shares.”  
*Cammer*, 711 F. Supp. at 1286.

“Second, it would be persuasive to allege a significant number of securities analysts followed and reported on a company’s stock during the class period.”  
*Cammer*, 711 F. Supp. at 1286.

“Third, it could be alleged the stock had numerous market makers.”  
*Cammer*, 711 F. Supp. at 1286.



“Fourth, as discussed, it would be helpful to allege the Company was entitled to file an S-3 Registration Statement in connection with public offerings ...”

*Cammer*, 711 F. Supp. at 1287.

“Finally, it would be helpful to a plaintiff seeking to allege an efficient market to allege empirical facts showing a cause and effect relationship between unexpected corporate events or financial releases and an immediate response in the stock price.”

*Cammer*, 711 F. Supp. at 1287.

“As previously noted, one of the most convincing ways to demonstrate efficiency would be to illustrate over time, a cause and effect relationship between company disclosures and resulting movements in stock price.”

*Cammer*, 711 F. Supp. at 1291.

### The Krogman Factors

95. In addition to the five *Cammer* factors that indicate market efficiency, the court in *DVI* also examined two factors set forth by the District court in *Krogman v. Sterritt* 202 F.R.D. 467 (N.D. Tex. 2001): 1) the company’s market capitalization, and 2) the stock’s float:

“In analyzing *DVI*’s common stock, the court also examined two factors set forth in *Krogman v. Sterritt*, (1) the company’s market capitalization; and (2) the size of the public float for the security.”

*DVI*, 2011 U.S. App. LEXIS 6302, \*24 n. 14 (internal citations omitted).

96. Market capitalization, the total value of all outstanding shares, equals the number of shares outstanding times the price per share. Reasonably, the larger the market capitalization, the more prominent and well known the company will be. Larger companies tend to attract wider analyst and news media coverage, and gain the attention of greater numbers of investors, including very large institutional investors. All of these characteristics, which accompany a large market capitalization, promote market efficiency.
97. The stock’s float is the number of shares outstanding, less shares held by insiders and affiliated corporate entities.<sup>27</sup> It is generally the number of shares available for trading by outside investors in the open market. Of course, float is highly correlated with market capitalization, but it focuses on the shares available for trading rather than all shares

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<sup>27</sup> For a discussion of the generally accepted definitions of shares outstanding and float, see *Float Adjustment Methodology*, Standard & Poor’s, August 2006.

outstanding. Stocks with large levels of float tend to trade more actively, attract more analyst and news media coverage, and garner the attention of greater numbers of investors, including large institutional investors. All of these characteristics, which accompany a high float level, promote market efficiency.

98. The District court in *Krogman*, and subsequently the Court of Appeals for the Fifth Circuit in *Unger v. Amedisys Inc.*, 401 F.3d 316 (5<sup>th</sup> Cir. 2005), evaluated one additional factor considered to be indicative of market efficiency, the typical bid-ask spread.
99. The bid-ask spread is the difference between the price at which market makers are offering to buy a security and the price at which they are offering the security for sale. For a security that is actively traded and for which information is readily available, the bid-ask spread will tend to be narrow. Moreover, a narrow bid-ask spread makes trading in the security less costly for investors, and thereby tends to attract greater interest, greater coverage, and greater volume. These conditions, in turn, are generally considered to promote market efficiency.

### **EFFICIENCY OF THE MARKET FOR PHARMACIA COMMON STOCK**

100. To assess whether or not the market for Pharmacia common stock was an efficient market, I analyzed the market and behavior of Pharmacia common stock, focusing on factors that are generally accepted to be indicative of market efficiency for a publicly traded security. These include the five *Cammer* factors and the three *Krogman* factors.

### **Trading Volume**

101. Throughout the Class Period, Pharmacia's common stock traded regularly and actively. On average, 4.6 million shares changed hands daily.<sup>28</sup> On one day alone, 16 July 2001, over 13.3 million shares traded.
102. In addition to average daily trading volume, another volume metric to consider in determining market efficiency is the percentage of outstanding shares that turn over each week. During the Class Period, the average weekly trading volume was 1.8% of shares

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<sup>28</sup> Financial data provided by CRSP.

outstanding.<sup>29</sup> This level of trading activity exceeds levels accepted by courts as being indicative of market efficiency for common stocks.<sup>30</sup> In the case of the common stock of Coated Sales, Inc., the *Cammer* Court cited the conclusion of Alan R. Bromberg and Lewis D. Lowenfels that “weekly trading of 2% or more of the outstanding shares would justify a strong presumption that the market for the security is an efficient one; 1% would justify a substantial presumption.”<sup>31</sup> Trading volume for Pharmacia common stock during the Class Period was well above the threshold for a substantial presumption of its market efficiency, and closer to the 2% threshold for a strong presumption.

103. Both in terms of average daily trading volume and on the basis of the percentage of outstanding shares traded weekly, the market for Pharmacia common stock was very active. Consistent with the *Cammer* opinion and economic theory, the active trading volume in Pharmacia’s common stock evinces the efficiency of the market for Pharmacia common stock over the course of the Class Period.

### **Analyst Coverage and Other Avenues of Information Dissemination**

#### **Analyst Coverage**

104. Securities analysts disseminate and interpret information about the companies they cover. Conducting research and providing valuation opinions, they help market participants acquire relevant information and understand its implications for valuation and investment decisions. Consequently, securities analysts facilitate the flow of information and the digestion of information within the marketplace. These functions promote market efficiency.
105. Pharmacia was the subject of broad analyst coverage during the Class Period. The Thomson Research database provides access to analyst reports on Pharmacia published by 18 different firms during the Class Period: ABN AMRO; Argus Research; Bear Stearns; Carnegie Group; CIBC; Credit Suisse First Boston; Deutsche Bank Securities; DLJ; ING Barings; Morgan Stanley; Paine Webber; PNC Advisors; Prudential; Raymond James; Robertson Stephens; SG Cowen; Solomon Smith Barney; and UBS Warburg.

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<sup>29</sup> Estimated by dividing the average daily volume by the average number of shares outstanding, times 5 (the number of trading days in a typical week).

<sup>30</sup> *Cammer*, 711 F. Supp. at 1286.

<sup>31</sup> *Cammer*, 711 F. Supp. at 1293 (internal citation omitted).

106. The Company's conference call transcripts for 25 April 2000, 25 July 2000, 30 October 2000, 12 February 2001, 25 April 2001, and 25 July 2001 show an additional 10 firms that were covering Pharmacia: Alliance Capital; Bank of America; BT Alex.Brown; Brown Brothers; Capital Research; Goldman Sachs; JP Morgan; Lincoln Capital; Merrill Lynch; and Oppenheimer.
107. Consequently, at least 28 firms covered Pharmacia during the Class Period.
108. Consistent with the *Cammer* opinion and financial economic principles, the widespread analyst coverage of Pharmacia is evidence of the efficiency of the market for Pharmacia's common stock during the Class Period.

#### Institutional Ownership and Buy-Side Analysis

109. Large investment firms generally employ financial analysts who conduct internal research on the stocks they buy. This internal research augments the more broadly disseminated research produced by investment banks and brokers. Consequently, institutional ownership of a company's stock indicates greater analyst coverage.
110. Moreover, published empirical research has established that high levels of institutional ownership are another indicator of market efficiency:

“Stocks with greater institutional ownership are priced more efficiently, and we show that variation in liquidity does not drive this result.

...

We find that greater institutional holdings are associated with improved efficiency, and this result is robust across different measures of efficiency, different econometric specifications, and a variety of controls. ... Overall, our findings imply that the presence of institutional investors improves the information environment of a firm.”

**“Institutional Investors and the Informational Efficiency of Prices,” by Ekkehart Boehmer and Eric K. Kelley, *The Review of Financial Studies*, 2009, pp. 3563, 3592.**

111. Vickers Stock Research Corporation (“Vickers”) provides data on institutional ownership of Pharmacia common stock. The data are compiled from the 13-F filings that major investment institutions are required to submit to the SEC. Major institutions are defined as firms or individuals that exercise investment discretion over the assets of others in excess of \$100 million. Large investment firms generally employ financial analysts who conduct

their own research on the stocks they buy. According to the Vickers data, at least 1,573 major institutions owned Pharmacia common stock during the Class Period.<sup>32</sup>

#### News Coverage and Other Information Dissemination Vehicles

112. The news media also facilitate the flow of material information to the marketplace thereby promoting market efficiency. In the case of Pharmacia, coverage by the news media was extensive. A search of the Factiva database established that at least 2,770 articles about the Company were published during the 476-day Class Period.<sup>33</sup>
113. The articles obtained from Factiva include published news articles and press releases. Information also emerged throughout the Class Period in the form of SEC filings, conference calls, and Company presentations. Therefore, during the Class Period, information about Pharmacia was readily available to market participants as there was a consistent flow of news issuing from news media, analysts, and various other sources.
114. Pharmacia was not an obscure company, escaping the notice of the news media, analysts, and investors. Rather, Pharmacia was large, well known, widely covered, and widely held. These facts strongly support a finding that the market for Pharmacia common stock was an efficient market during the Class Period.

#### Market Makers and Listing on the New York Stock Exchange

115. The number of market makers is one of the factors the *Cammer* Court determined indicates market efficiency. The subject company of the lawsuit in the *Cammer* case, Coated Sales, Inc., was listed on the NASDAQ, an electronic stock exchange that makes use of multiple competing market makers. Market makers are financial intermediaries who trade in a particular security, standing ready to buy and sell with investors and institutions. Consequently, for a NASDAQ-listed stock, a large number of market makers implies that many market participants are trading that particular stock. It further implies a high degree of liquidity. With a large number of market makers it is generally easy for investors to execute trades in a timely fashion and with reasonable transaction costs.

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<sup>32</sup> At least 1,573 institutional investors held Pharmacia common stock according to filings that reported holdings as of 30 June 2000, 30 September 2000, 31 December 2000, 31 March 2001, and 30 June 2001. Additional institutions may have held Pharmacia common stock during the Class Period, though not on these quarterly reporting dates.

<sup>33</sup> Based on a Factiva search of “All Sources” for articles published during the Class Period where “Pharmacia Corporation” was the “Company” search field parameter.

116. The *Cammer* Court’s understanding that the market-making infrastructure of a stock market is indicative of its efficiency, or lack thereof, makes the fact that Pharmacia common stock traded on the venerable New York Stock Exchange highly relevant.
117. The NYSE is one of the most renowned, most liquid, and most efficient forums for trading stocks in the world. Stocks on the NYSE are traded under the supervision of a lead market maker known as a “specialist.” Specialists are responsible for maintaining a fair and orderly market for each security to which they are assigned.<sup>34</sup>
118. In fact, citing Bromberg and Lowenfels, the *Cammer* Court explicitly acknowledged the importance of an NYSE listing and the implications of such a listing on market efficiency.

“We think that, at a minimum, there should be a presumption – probably conditional for class determination – that certain markets are developed and efficient for virtually all the securities traded there: the New York and American Stock Exchanges, the Chicago Board Options Exchange and the NASDAQ National Market System.”  
*Cammer*, 711 F. Supp. at 1292 (quoting Bromberg and Lowenfels, *Securities Fraud and Commodities Fraud*, §8.6, 1988).

119. The *DVI* Court concurred that a listing on the New York Stock Exchange generally indicates market efficiency.

“Accordingly, the listing of a security on a major exchange such as the NYSE or the NASDAQ weighs in favor of a finding of market efficiency.”  
*DVI*, 2011 U.S. App. LEXIS 6302, at \*23.

120. While specialists are the most important market makers for NYSE stocks, they are not the only market makers. Generally, numerous brokers and dealers also make markets in NYSE-listed stocks, and the exchange specialist facilitates their market making activity.
121. The fact that it traded on the NYSE is strong evidence that Pharmacia common stock traded in an efficient market. Pharmacia’s listing on the NYSE gave its stock access to a highly developed network of brokers and dealers and the oversight of an NYSE-designated specialist. These facts are important evidence of the efficiency of the market for Pharmacia stock.

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<sup>34</sup> “Organization and Functioning of Securities Markets,” by Frank Reilly and Keith Brown, in *Equity and Fixed Income CFA Program Curriculum*, vol. 5, Pearson Custom Publishing, 2008.

**S-3 Registration Eligibility**

122. The *Cammer* opinion noted that S-3 registration is indicative of market efficiency because a company is entitled to S-3 registration when, among other things, it has filed Exchange Act reports for a specified length of time and has outstanding float above a certain value. At the time of the *Cammer* opinion, the conditions for S-3 registration were that a company filed financial reports with the SEC for 36 months and had outstanding float over \$150 million held by non-affiliates, or \$100 million of float coupled with annual trading volume exceeding 3 million shares. The *Cammer* court noted that the filing requirement ensured that financial data were available to market participants, and the size and volume requirements indicated that many market participants would have examined the information.

“Proposed Form S-3 recognizes the applicability of the efficient market theory to the registration statement framework with respect to those registrants which usually provide high quality corporate reports, including Exchange Act reports, and whose corporate information is broadly disseminated, because such companies are widely followed by professional analysts and investors in the market place. Because of the foregoing observations made by the SEC, the existence of Form S-3 status is an important factor weighing in favor of a finding that a market is efficient.”

*Cammer*, 711 F. Supp. at 1284-85 (internal citation omitted).

“The ‘public float’ aspect of the Form S-3 requirements ensures that enough investors have in fact read the previously filed document.”

*Cammer*, 711 F. Supp. at 1285.

“Again, it is the number of shares traded and value of shares outstanding that involve the facts which imply efficiency.”

*Cammer*, 711 F. Supp. at 1287.

123. The rules as of today grant S-3 eligibility to companies that have at least 12 months of filings and \$75 million of float.<sup>35</sup>

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<sup>35</sup> “Eligibility of Smaller Companies to Use Form S-3 or F-3 for Primary Securities Offerings,” by the U.S. Securities and Exchange Commission, 28 January 2008.

Float

124. A company's float is the number or value of shares that can potentially trade freely in the marketplace. It is generally defined as the number or value of outstanding shares, minus insider holdings and shares owned by affiliated corporate entities.
125. I computed Pharmacia's common stock float from share data reported in Pharmacia's SEC filings and stock price data provided by CRSP.<sup>36</sup>
126. Pharmacia common stock float averaged \$68.2 billion during the Class Period, far exceeding the level required for S-3 registration. The Company's float ranged between \$78.4 billion and \$54.4 billion during the Class Period. Even at its minimum, Pharmacia's common stock float was well over the threshold for S-3 registration under both the current rules and the more stringent original rules applicable at the time of the *Cammer* opinion.

Reporting

127. While Pharmacia, in its merged incarnation, was created just prior to the Class Period, both Old Monsanto and PNU, its constituent entities, had been filing financial reports with the SEC for a sufficient number of years prior to the Class Period to satisfy the S-3 requirement. Post-merger, Pharmacia remained current with SEC filings. Consequently, many years of past financial data on the Company's components were available to investors throughout the Class Period.
128. That Pharmacia satisfied the reporting requirement throughout the Class Period is evident in the Form S-3A the Company filed on 2 November 2000 to amend its Form S-3, filed on 20 September 2000. In the amendment, Pharmacia cited and incorporated by reference its Form 10-K for the year ended 31 December 1999, filed on 20 March 2000, as well as quarterly reports on Form 10-Q/A for the quarters ended 31 March 1999 through 30 September 1999.<sup>37</sup> In the same S-3A filing, the Company cited and incorporated by reference three years of audited Monsanto financial statements.

“The financial statements of Monsanto Company (subsequently renamed Pharmacia Corporation) as of December 31, 1999 and 1998, and for each

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<sup>36</sup> According to Proxy Statements filed 22 May 2000 and 16 March 2001, insiders held 4,609,723 and 2,202,778 shares as of 4 May 2000 and 5 March 2001, respectively. For the first 12 days of the Class Period, I used the 4,609,723 shares reportedly held as of 4 May 2000 as the approximate number of shares held by insiders after the merger.

<sup>37</sup> Pharmacia Corporation Form S-3A, filed 2 November 2000, pp. 14-15.



of the three years in the period ended December 31, 1999, incorporated by reference in this prospectus/registration statement have been audited by Deloitte & Touche LLP, independent auditors, as stated in their report which is incorporated herein by reference, and have been so incorporated by reference in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.”

**Pharmacia Corporation Form S-3A, filed 2 November 2000, pp. 13-14.**

#### Eligibility

129. Not only was Pharmacia eligible to undertake S-3 registration during the Class Period, it did file a Form S-3 registration on 20 September 2000 followed by a Form S-3A on 2 November 2000.<sup>38</sup>
130. Consistent with the *Cammer* opinion, Pharmacia’s eligibility to file an S-3 registration is evidence of the efficiency of the market for Pharmacia common stock during the Class Period.

#### **Krogman Factors**

131. In addition to the five *Cammer* factors that indicate market efficiency, I also examined Pharmacia stock and its market with respect to the three additional *Krogman* factors.

#### Market Capitalization

132. During the Class Period, Pharmacia’s market capitalization averaged over \$68.4 billion.
133. The Ibbotson *Stocks, Bonds, Bills & Inflation (SBBBI)* publications present annual statistics that rank the size of all public companies by market capitalization. Ibbotson groups public companies into deciles, so that the 1<sup>st</sup> decile contains the largest 10% of all public companies listed on the NYSE, American Stock Exchange, and NASDAQ, while the 10<sup>th</sup> decile contains the smallest 10%.
134. Pharmacia’s average market capitalization of \$68.4 billion ranked in the 1<sup>st</sup> decile relative to all other publicly-traded companies in 2000 and 2001. This position means that

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<sup>38</sup> Pharmacia Corporation Form S-3, filed 20 September 2000; Pharmacia Corporation Form S-3A, filed 2 November 2000.

Pharmacia's market capitalization was larger than the market capitalizations of more than 90% of all other publicly-traded companies in the United States.<sup>39</sup>

135. Consistent with the *Krogman* Court opinion, Pharmacia's large average market capitalization is further evidence of the efficiency of the market for Pharmacia stock.

#### Outstanding Float Ratio

136. The magnitude of Pharmacia's float, as discussed above in relation to the S-3 eligibility factor, is likewise indicative of market efficiency.
137. For Pharmacia, the number of insider shares was a relatively small percentage of all outstanding shares. The maximum number of insider shares over the course of the Class Period divided by the minimum number of shares outstanding is 0.37%. This ratio implies that Pharmacia's float comprised nearly all its outstanding shares throughout the Class Period.
138. The *Krogman* opinion cited a high ratio of float to outstanding shares as an indicator of market efficiency. With respect to this measure, Pharmacia clearly exhibited market efficiency.

#### Bid-Ask Spread

139. From CRSP I obtained daily closing bid and ask quotes for Pharmacia stock.
140. I measured the percentage bid-ask spread as the difference between the ask and bid quotes, divided by the average of the bid and ask quotes, which is the standard way of measuring percentage bid-ask spreads in the finance literature. Exhibit-5 presents Pharmacia's bid-ask spread data.
141. The average bid-ask spread for Pharmacia stock over the course of the Class Period was 1.17%.
142. By comparison, the average month-end bid-ask spread over the course of the Class Period for all stocks in the CRSP database was 3.93%. Therefore, Pharmacia's average bid-ask spread was narrower than the mean level among all other CRSP stocks, which comprised stocks traded on the NYSE, Amex, NASDAQ, and NYSE Arca.

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<sup>39</sup> *Ibbotson 2000 Stocks, Bonds, Bills & Inflation (SBBBI) 2000 Yearbook*, Ibbotson Associates, 2000, and *Ibbotson 2001 Stocks, Bonds, Bills & Inflation (SBBBI) 2001 Yearbook*, Ibbotson Associates, 2001.

143. On only one day (20 April 2001) out of the Class Period's 328 trading days was Pharmacia's bid-ask spread wider than the 3.93% average for all other CRSP stocks. Even then, at 3.98%, Pharmacia's bid-ask spread was only marginally higher than the average among other CRSP stocks. Moreover, Pharmacia's trading volume on that day was 7.48 million shares, indicating that the slightly higher bid-ask spread did not impede active trading.
144. The bid-ask spread in the market for Pharmacia stock over the course of the Class Period was lower than the typical bid-ask spreads exhibited by other publicly-traded stocks. Pharmacia's narrow bid-ask spreads support a conclusion of market efficiency.

### **EMPIRICAL EVIDENCE OF PHARMACIA COMMON STOCK MARKET EFFICIENCY**

#### **Special Importance of the Empirical Factor**

145. Of the five *Cammer* factors, the empirical factor was cited by the *Cammer* Court as "one of the most convincing ways to demonstrate efficiency":

"As previously noted, one of the most convincing ways to demonstrate efficiency would be to illustrate, over time, a cause and effect relationship between company disclosures and resulting movements in stock price."  
*Cammer*, 711 F. Supp. at p. 1291.

146. The *DVI* Court agreed with the importance of the empirical factor:

"However, because an efficient market is one in which 'information important to reasonable investors ... is immediately incorporated into stock prices,' the cause-and-effect relationship between a company's material disclosures and the security price is normally the most important factor in an efficiency analysis."  
*DVI*, 2011 U.S. App. LEXIS 6302, at \*24 (internal citation omitted).

147. The special weight the *Cammer* and *DVI* Courts accorded the empirical factor is justified by economic principles, for the empirical factor focuses on the essence of market efficiency whereas the other factors are indicators that generally signal market efficiency.

**Event Study Analysis**

148. In order to investigate the empirical efficiency of the market for Pharmacia common stock, I conducted an event study. An event study examines whether a security price reacts appropriately to the release of new information. An appropriate and significant cause and effect relationship between the release of new material information and stock price movements demonstrates market efficiency.
149. The event study is the paramount tool for testing market efficiency, as Eugene Fama attests:
- “The cleanest evidence on market-efficiency comes from event studies, especially event studies on daily returns. When an information event can be dated precisely and the event has a large effect on prices, the way one abstracts from expected returns to measure abnormal daily returns is a second-order consideration. As a result, event studies give a clear picture of the speed of adjustment of prices to information.”  
**“Efficient Capital Markets: II,”** by Eugene F. Fama, *Journal of Finance*, 1991, p. 1607.
150. Event study analysis is one of the most commonly used analytic methodologies employed by finance researchers. MacKinlay [1997] presents an excellent description and examples of the methodology and writes about how it is generally accepted and widely used in academic research.<sup>40</sup> Tabak and Dunbar [2001] write about how the methodology is generally accepted and widely used in forensic applications.<sup>41</sup>
151. An event study measures how much a stock price rises or falls in response to new information. It first determines how much of a stock price change cannot be explained by market and sector factors. The portion of a stock price change that cannot be attributable to market and sector factors is called the residual stock price movement or “residual return.” The event study isolates the residual return and also tests whether or not the residual return can reasonably be explained as merely a random fluctuation.
152. If the stock return is deemed statistically significant, it means that the stock price movement cannot be attributed to market and sector factors, or to random volatility, but rather was likely caused by company-specific information. Such proof of a cause and effect

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<sup>40</sup> “Event Studies in Economics and Finance,” A. Craig MacKinlay, *Journal of Economic Literature*, March 1997.

<sup>41</sup> “Materiality and Magnitude: Event Studies in the Courtroom,” by David Tabak and Frederick Dunbar, in *Litigation Services Handbook*, 3<sup>rd</sup> edition, John Wiley & Sons, New York, 2001.

relationship between new material information and the reaction in the stock price establishes market efficiency.

Event Selection Criterion

153. Not only did the *DVI* Court single out the empirical factor as most important, but it also recognized the special importance of the disclosure events:

“[T]he cause-and-effect relationship between a company’s material disclosures and the security price is normally the most important factor in an efficiency analysis.”  
*DVI*, 2011 U.S. App. LEXIS 6302, at \*24.

154. The *Cammer* Court also recognized the special importance of the disclosures and the specific information allegedly misrepresented or omitted that is the subject of the litigation:

“The central question under the fraud on the market theory is whether the stock price, *at the time a plaintiff effected a trade*, reflected the ‘misinformation’ alleged to have been disseminated.”  
*Cammer*, 711 F. Supp. at 1282 (emphasis in original).

“As previously noted, one of the most convincing ways to demonstrate efficiency would be to illustrate over time, a cause and effect relationship between company *disclosures* and resulting movements in stock price.”  
*Cammer Opinion*, 711 F. Supp. at p. 1291 (emphasis added).

155. Consequently, the empirical behavior of Pharmacia common stock following the curative disclosures warrants focus in the event study testing the efficiency of the market for Pharmacia stock.
156. Forensic financial analysts David Tabak and Frederick Dunbar concur that disclosure events are reasonable choices for the focus of the event study:

“Many texts discuss how to perform an event study. While there are some differences in exposition, there is a uniform agreement in the literature on the necessary steps and general procedures to be followed. First, one must identify the event or events to be studied. In securities fraud cases, the events of interest usually include all the alleged disclosures of fraud and/or the dates when fraudulent statements were made.”  
“Materiality and Magnitude: Event Studies in the Courtroom,” by David Tabak and Frederick Dunbar, in *Litigation Services Handbook*, 3<sup>rd</sup> ed., John Wiley & Sons, New York, 2001, p. 7.

157. Though Tabak and Dunbar suggest that either disclosures or misrepresentations can be selected as events for testing market efficiency, I elected to test the disclosure events. Disclosures, by their nature, generally entail the release of new information that changes the market's understanding of material facts, and therefore could reasonably be expected to move the security price. Misrepresentations, on the other hand, are often omissions or announcements that conceal adverse developments. As such, misrepresentations may introduce or maintain artificial inflation by preventing a security price from falling rather than causing the price to rise significantly. Consistent with this analysis, courts have accepted a focus on disclosure events:

“Given the common-law roots of the securities fraud action (and the common-law requirement that a plaintiff show actual damages), it is not surprising that other Courts of Appeals have rejected the Ninth Circuit's ‘inflated purchase price’ approach to proving causation and loss. See, e.g., *Emergent Capital*, 343 F.3d, at 198 (inflation of purchase price alone cannot satisfy loss causation); *Semerenco*, 223 F.3d, at 185 (same); *Robbins*, 116 F.3d, at 1448 (same); cf. *Bastian*, 892 F.2d, at 685. Indeed, the Restatement of Torts, in setting forth the judicial consensus, says that a person who ‘misrepresents the financial condition of a corporation in order to sell its stock’ becomes liable to a relying purchaser ‘for the loss’ the purchaser sustains ‘when the facts ... become generally known’ and ‘as a result’ share value ‘depreciate[s].’ § 548A, Comment b, at 107.”

*Dura Pharms. Inc. v Broudo*, 544 U.S. 336, 344, 125 S. Ct. 1627 (2005).

“And, of course, the materiality of the alleged misrepresentations is self-evident when we look at the market's negative reaction – to the tune of a nine-percent drop in stock price in three days – when defendants' analysis of the CLASS study was questioned in February 2001.”  
*Alaska Electrical Pension Fund v. Pharmacia Corp.*, 554 F.3d 342, 352 (3<sup>rd</sup> Cir. 2009).

#### Disclosure Events

158. I reviewed the Complaint, the Third Circuit Opinion, and a wide variety of information sources, including news articles, press releases, FDA reviewer reports, equity analyst reports, and SEC filings to determine when corrective information related to the alleged misrepresentations and omissions was disseminated. The following is a list of the event dates selected using this criterion:

- i. 6-8 February 2001 – The FDA posted its reviews of the CLASS study results on the FDA website. According to the FDA Advisory Committee, the full CLASS trial did not show Celebrex to have a “meaningful safety advantage” over ibuprofen or diclofenac. The FDA panel consequently did not recommend any change to the GI warning on the Celebrex label.
- ii. 6-8 August 2001 – The *Washington Post* reported on Sunday, 5 August 2001, that the CLASS results presented in the *JAMA* article were drawn from only six months of data, whereas the CLASS study had produced more than a year of data. The article indicated that the misrepresentations and omissions related to the CLASS study may have been committed fraudulently.

#### Length of Event Window

- 159. The finance literature acknowledges that the market requires different amounts of time to process different types of information. When the timing of the information delivery is expected and when the type of information conforms to what is commonly analyzed, the processing tends to be quicker.
- 160. The Patell and Wolfson [1984] study is often cited as an authoritative examination of the normal speed of price adjustments for publicly traded stocks.<sup>42</sup> Patell and Wolfson focused their study on large companies that were actively traded and closely watched, representing firms whose markets are most likely efficient. They examined price reactions to earnings and dividend announcements.

“We should emphasize that our sample firms are large, actively traded, and closely watched.”

**“The Intraday Speed of Adjustment of Stock Prices to Earnings and Dividend Announcements,”** by James M. Patell and Mark A. Wolfson, *Journal of Financial Economics*, 1984, p. 250.

“This paper examines the effects of earnings and dividend announcements on the intraday behavior of stock prices.”

*Ibid.*, p. 223.

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<sup>42</sup> “The Intraday Speed of Adjustment of Stock Prices to Earnings and Dividend Announcements,” by James M. Patell and Mark A. Wolfson, *Journal of Financial Economics*, 1984.

161. Nonetheless, Patell and Wolfson found reactions to earnings announcements often persisted into the second day following the announcement event. They noted that for less regular news, the price adjustment interval could be “significantly longer.”

“However, for the earnings announcements we also find significantly elevated returns during the overnight period following the release and at the opening of trading on the next day.”

**“The Intraday Speed of Adjustment of Stock Prices to Earnings and Dividend Announcements,”** by James M. Patell and Mark A. Wolfson, *Journal of Financial Economics*, 1984, p. 224.

“The evening following the announcement provides an opportunity for news to be disseminated to investors who are unable to execute intraday trading strategies, and their actions may affect the overnight price change and the opening trades of the next day.”

*Ibid.*, p. 235.

“It is possible that the adjustment intervals would be significantly longer for smaller firms, or for other, less regular announcements made by our sample firms.”

*Ibid.*, p. 250.

162. Earnings announcements are generally scheduled and are therefore expected. The core information such announcements deliver – earnings, revenues, and outlook – is of the type that analysts anticipate, are accustomed to receiving, and generally focus upon. Because it meets the timing and type criteria, earnings information is of the sort that would be processed by the market most rapidly. Patell and Wolfson stated that less regular announcements could take longer.
163. Unlike typical earnings announcements, the reports and analyses of the CLASS study comprised voluminous and complex scientific, medical, and statistical information. Company documents acknowledge this fact:

“The Advisory Board seemed to experience difficulty in analyzing and providing their advice on these large complex trials.”

**“FW: FDA Advisory Board Meetings on Celebrex and Vioxx, Feb. 7<sup>th</sup> and 8<sup>th</sup>,”**  
**email from Alicia Byer, 14 February 2001, Exhibit-316 at [DEFS 03101711].**



“Due to the complexity of the CLASS data, the advisory panel on day one (February 7) experienced difficulty interpreting the results.”

**“Q&A: FDA Advisory Committee Hearing on Proposed GI Safety Label Revisions for Celebrex®,” dated 9 February 2001, Exhibit-262 at [DEFS 00754326].**

“This was an extremely rigorous and complex trial, which made it difficult for the committee to analyze.”

**“Pharmacia/Pfizer Inc Statement on the FDA Arthritis Advisory Committee Meeting,” dated 7 February 2001, Exhibit-314 at [DEFS 03101545].**

164. The Circuit Court in this case likewise noted that the CLASS data at the center of the present case were highly complex and voluminous.

“But the staff reports span over 250 pages of highly complex scientific and statistical analysis.”

***Pharmacia*, 554 F.3d at 349 (internal citations omitted).**

165. Not only were the disclosure events in this case complex, but their timing was irregular. Neither the posting of the FDA briefing reports on the agency’s website, nor the publication of the *Washington Post* exposé, conformed to a preannounced schedule.
166. Consistent with Patell and Wolfson’s conclusions, therefore, the complex and irregularly timed disclosure events in the present case should take the market longer to process than typical earnings announcements. Accordingly, the price reaction would be more protracted.
167. Patell and Wolfson noted that some of the price adjustment interval is attributable to the time it takes for the news to be disseminated.<sup>43</sup> The *Cammer* and *DVI* Courts acknowledged that analyst coverage facilitates market efficiency. It follows logically that when analysts require more time to analyze a particular release of information, perhaps because it is complex or unexpected, the efficient market price response will also require additional time.
168. In fact, in this case, several analyst reports that facilitated the processing and dissemination of the new information about Celebrex that was released on 6 February 2001 and 7 February 2001 were published on 8 February 2001. The time required for analysts to digest

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<sup>43</sup> Patell and Wolfson stated, “the evening following the announcement provides an opportunity for news to be disseminated to investors who are unable to execute intraday trading strategies, and their actions may affect the overnight price change and the opening trades of the next day.” “The Intraday Speed of Adjustment of Stock Prices To Earnings and Dividend Announcements,” by James M. Patell and Mark A. Wolfson, *Journal of Financial Economics*, 1984, p. 235.

the new information speaks to the complexity and volume of the information. Moreover, the time required by analysts to write and distribute their reports extended the time it took the market to fully comprehend the import of the new information.

169. The *DVI* Court recognized that an efficient market does not necessarily require that market participants be able to fully process complex information instantaneously. The *DVI* Court held:

“We have addressed the speed with which information is incorporated into market price and explained that because a perfectly efficient market is not attainable, we do not require that public information be absorbed ‘instantaneously.’ Applying this standard, we have held that a market is inefficient when a price does not decrease within four days following an alleged corrective disclosure.”

*DVI*, 2011 U.S. App. LEXIS 6302, at \*27 (internal citations omitted).

“That some information took two days to affect the price does not undermine a finding of efficiency.”

*DVI*, 2011 U.S. App. LEXIS 6302, at \*28.

170. The position of the *DVI* Court is consistent with the academic and professional finance literature explaining that event windows should not necessarily be limited to a single day, but rather, as circumstances dictate, may extend to multiple days.

“In securities fraud cases, many experts have adopted the convention of looking at one-day, two-day, or five-day periods following an announcement.”

**“Materiality and Magnitude: Event Studies in the Courtroom,”** David I. Tabak and Frederick C. Dunbar in *Litigation Services Handbook, The Role of the Financial Expert*, 3rd ed., edited by Roman L. Weil, Michael J. Wagner, and Peter B. Frank, John Wiley & Sons, Inc., 2001, p. 19.4.

“The initial task of conducting an event study is to define the event of interest and identify the period over which the security prices of the firms involved in this event will be examined – the event window. For example, if one is looking at the information content of an earnings with daily data, the event will be the earnings announcement and the event window will include the one day of the announcement. It is customary to define the event window to be larger than the specific period of interest. This permits

examination of periods surrounding the event. In practice, the period of interest is often expanded to multiple days, including at least the day of the announcement and the day after the announcement.”

“Event Studies in Economics and Finance,” A. Craig MacKinlay, *Journal of Economic Literature*, March 1997, pp. 14-15.

171. Recognizing that stock price reactions may persist beyond the first or even second day following an event, published empirical studies commonly examine event windows longer than one day and run “cumulative event studies” on the multiday windows. There are many examples of such event studies in the academic literature. In fact, one of the very first published event studies, conducted by recognized leaders in academic finance, was a cumulative event study. “The Adjustment of Stock Prices to New Information,” by Eugene Fama, Lawrence Fisher, Michael Jensen, and Richard Roll, which appeared in the *International Economic Review* in 1969, examined the reaction of stock prices to stock splits. These researchers ran a cumulative event study that aggregated stock price reactions over time and across different companies.
172. The seminal Fama, Fisher, Jensen, and Roll [1969] article spawned a great many academic studies using their cumulative event study methodology. These publications are well represented and respected in the scholarly literature.
173. In a survey of academic studies, Robert Bruner looked at numerous publications that utilized the cumulative event study methodology. Of the 21 articles he reviewed, 16 used event windows of five days or longer.<sup>44</sup>
174. In a cumulative event study, the threshold for statistical significance rises as the length of the event window is increased. Therefore, the price reaction necessary to prove significance for a multiday event window is considerably higher than for a one-day event window.
175. Given the facts and circumstances of the disclosure events at issue in this case, to be consistent with generally accepted financial principles and practice, and consistent with the Third Circuit Court in *DVI*, I examined three-day windows following the disclosure events. I tested the price reactions on a cumulative basis as well as single days individually.

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<sup>44</sup> “Does M&A Pay? A Survey of Evidence for the Decision-Maker,” by Robert F. Bruner, *Journal of Applied Finance*, Spring/Summer 2002.

Controlling for Potentially Confounding Factors: Removing Factors that Impact the Chemicals and Agricultural Business of New Monsanto

176. As discussed above, over the course of the Class Period, Pharmacia's businesses included not only the pharmaceuticals business at issue in this case, but also the chemicals and agricultural business that was ultimately spun off with New Monsanto. From 18 October 2000 onward, New Monsanto stock was issued and traded freely in the marketplace, making it possible to observe that company's value on an aggregate and per share basis. It was further possible, therefore, to remove from the value of Pharmacia the value of its holdings in New Monsanto. In this way, the effect that any chemicals and agricultural related news might have wielded on the value of Pharmacia stock would be removed.
177. Removing the value of Pharmacia's holdings in New Monsanto focused the event study analysis on the pharmaceuticals business and eliminated the potential for the unrelated business to obscure the impact of pharmaceuticals news. That is, if the value of the New Monsanto holdings were not removed, information about Celebrex, for example, might impact the valuation of the pharmaceuticals portion of Pharmacia's business, but this impact could be obscured, or muted, by the weight of the chemicals and agricultural portion of the business.
178. The October 2000 Spin-Off initiated trading in New Monsanto stock even though Pharmacia maintained ownership of approximately 85.3% of that company. Using the market values of the New Monsanto stock, I computed the value of Pharmacia's aggregate holdings in New Monsanto, subtracted this value from Pharmacia's market capitalization, and then divided the remaining value by the number of Pharmacia shares outstanding. The result of these computations is the per share value of Pharmacia's pharmaceuticals business alone.
179. For example, on 15 November 2000, the price of New Monsanto stock was \$24.375 per share. Pharmacia owned 220 million shares of New Monsanto, representing a stake worth \$5,362,500,000 (equal to 220,000,000 shares times \$24.375 per share). The market capitalization of Pharmacia as a combined company was \$73,938,181,250, equal to the 1,269,325,000 outstanding shares of Pharmacia times the market price of \$58.25 per share. Subtracting the \$5,362,500,000 value of the New Monsanto stake from the \$73,938,181,250 market capitalization indicates that the value of Pharmacia stock

excluding New Monsanto was \$68,575,681,250. Per Pharmacia share, the value of the Company excluding New Monsanto was therefore \$54.03 (\$68,575,681,250 divided by 1,269,325,000 shares).

180. For convenience of exposition, I term the per share value of Pharmacia's pharmaceuticals business, thusly computed, the "Pharmacia Pharmaceutical Stock Price." Exhibit-6 presents the time series of the Pharmacia Pharmaceuticals Stock Price along with the logarithmic returns based on these prices.

Controlling for Potentially Confounding Factors: Removing the Market and Sector Effects

181. One component of an event study is to determine how much of a company's stock returns are attributable to market and sector effects, so that these factors can be isolated and removed.
182. The method, which is generally accepted and widely used in econometric modeling, first involves running a regression to determine how the company's stock price typically behaved in relation to the overall stock market and its industry sector. Then, the regression model is used to determine how much of each event day's actual return is explained by the market and sector factors (the "explained return"). The actual return minus the explained return is the residual return.
183. In this case, the regression analysis removed from the returns on the Pharmacia Pharmaceuticals Stock Price that portion explained by the overall stock market and pharmaceuticals sector, thereby isolating the Pharmacia Pharmaceuticals Stock Price residual returns.
184. I ran the regression modeling the Pharmacia Pharmaceuticals Stock Price returns as a function of: 1) a constant term, 2) the returns of the overall stock market, and 3) the returns of a pharmaceuticals sector index. For the overall stock market factor I used the CRSP Market Total Return Index ("Market Index"), which is a generally accepted and widely used measure of the overall stock market performance. The Market Index appropriately incorporates payment of dividends by the constituent companies.
185. For the pharmaceuticals industry sector, I constructed an index ("Pharmaceutical Index") identical to the Dow Jones U.S. Pharmaceutical Index ("DJ Pharma Index"), with Pharmacia, Pfizer, and Merck removed. That is, I obtained from Dow Jones the

constituents of the DJ Pharma Index in 2000 and 2001 and computed a value-weighted index of the remaining constituents.

186. Pharmacia was excluded from the sector index because it is the subject company, and the study aims at identifying rather than controlling for the impact of news about Pharmacia. Pfizer co-marketed Celebrex. Because the study aims at identifying rather than controlling for the impact of news about Celebrex, it is necessary to remove Pfizer from the sector index. Similarly, Merck was excluded because it sold a competing COX-2 inhibitor, Vioxx.
187. The levels and returns of the Market Index and the Pharmaceutical Index are presented in Exhibit-7.
188. I ran the regression on daily returns covering the period 19 October 2000 through 18 October 2001. The estimation period begins on 19 October 2000 as this was the second day on which New Monsanto traded in the marketplace, which was therefore the first day on which the Pharmacia Pharmaceutical Stock Price return could be computed. The end of the estimation period was selected to be consistent with the widely accepted standard of using a one-year estimation period, when possible.
189. I used dummy variables for each day in the three-day window of each disclosure event to control for potentially abnormal returns on the disclosure dates being tested in the event study. Using an estimation period that surrounds the events of interest, and using dummy variables to control for the event dates in the regression estimation so that the model parameters properly reflect typical stock price movements, is a widely used and generally accepted methodology.<sup>45</sup>

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<sup>45</sup> See also: "Event Studies with a Contaminated Estimation Period," by Nihat Aktas, Eric de Bodt and Jean-Gabriel Cousin, *Journal of Corporate Finance*, 2007; "Measuring the Effects of Regulation with Stock Price Data," by John J. Binder, *The RAND Journal of Economics*, 1985; "Intervention Analysis with Applications to Economic and Environmental Problems," by G. E. P. Box and G. C. Tiao, *Journal of the American Statistical Association*, 1975; "Testing for Market Efficiency: A Comparison of the Cumulative Average Residual Methodology and Intervention Analysis," by David F. Larcker, Lawrence A. Gordon, and George E. Pinches, *Journal of Financial & Quantitative Analysis*, 1980; "Measuring Abnormal Performance: The Event Parameter Approach Using Joint Generalized Least Squares," by Paul H. Malatesta, *The Journal of Financial and Quantitative Analysis*, 1986; "Conditioning the Return-Generating Process on Firm-Specific Events: A Discussion of Event Study Methods," by Rex Thompson, *The Journal of Financial and Quantitative Analysis*, 1985.

“Three general choices for the placement of an estimation window are before the event window, surrounding the event window, and after the event window.”

“Materiality and Magnitude: Event Studies in the Courtroom,” David I. Tabak and Frederick C. Dunbar in *Litigation Services Handbook: The Role of the Financial Expert*, 3rd ed., edited by Roman L. Weil, Michael J. Wagner, and Peter B. Frank, John Wiley & Sons, Inc., 2001, p. 19.19.

“... [O]ne might consider creating a dummy [variable] to model the timing of important news announcements,”

*Market Models: A Guide to Financial Data Analysis*, Carol Alexander, John Wiley & Sons Ltd, 2001, p. 440.

190. All returns used in the event study are logarithmic returns – that is, the natural logarithm of the ratio of the current day’s closing price plus dividends to the previous day’s closing price. Logarithmic returns are commonly used in event studies and equity analysis. Analysts and researchers generally use logarithmic returns instead of percent price changes because of various computational advantages.<sup>46</sup>
191. The regression results, presented in Exhibit-8, show that returns on the Pharmacia Pharmaceutical Stock Price were significantly related to the returns of the Pharmaceutical Index, but not to the Market Index. The non-significance of the market index is not uncommon in stock return modeling that includes a sector index, as the sector index often captures the market effect as well as the sector effect.
192. I computed the explained portion of the Pharmacia Pharmaceutical Stock returns by adding: 1) the estimated regression intercept term, 2) the respective day’s Market Index return multiplied by the regression’s Market Index coefficient, and 3) the Pharmaceutical Index return multiplied by the regression’s Pharmaceutical Index coefficient. The residual return is the actual return minus the explained return.

#### t-test

193. For each event, a statistical test called a *t*-test was conducted to determine whether the residual return can be explained by random volatility, or alternatively must have been caused by Company-specific information. A *t*-test compares the residual return following an event date to the typical residual returns exhibited in the estimation period. If the event residual return is far greater (positively or negatively) than the typical residual return, the *t*-

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<sup>46</sup> The Appendix presents the mathematical formula for the logarithmic return and a discussion of the measure.



test indicates that the residual return in question cannot have been caused by random volatility alone – *i.e.*, it is statistically significant.<sup>47</sup>

194. The event study results are presented below and summarized in Exhibit-9.

Event Study Results: 6-8 February 2001

195. On or about 6 February 2001, the FDA posted on its website results from the CLASS trials from the entire study period and its analysis of the results. The following day, 7 February 2001, the FDA Advisory Committee, on the basis of the results from the full CLASS study, recommended that the agency not approve the label change for Celebrex that Pharmacia had requested.
196. Over the three-day period, 6-8 February 2001, the Pharmacia Pharmaceutical Stock Price fell 11.18% (on a logarithmic return basis). Over the same period, the Market Index return was -1.48%, and the Pharmaceutical Index return was 1.00%. The three-day explained return for the Pharmacia Pharmaceutical Stock Price according to the regression model is positive 0.64%, which is the change one would expect in the value of the Pharmacia Pharmaceutical Stock Price on account of market and sector effects, absent any Company-specific information.
197. The difference between the actual three-day return of -11.18% and the explained return of 0.64% is -11.81%, which is the residual three-day return for the Pharmacia Pharmaceutical Stock Price.<sup>48</sup> This three-day residual return of -11.81% from 6 February through 8 February 2001 is associated with a *t*-statistic value of -3.54. The likelihood of obtaining a residual return of this magnitude as a result of random volatility alone is only 0.05% (p-value equals 0.0005). Because it is so unlikely that the -11.81% residual return could have been caused by random volatility, the random volatility explanation can be ruled out. At the 0.05% significance level (equivalent to a 99.95% confidence level) therefore, the three-day residual return is statistically significant.

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<sup>47</sup> The test is called the *t*-test because it involves the computation of a *t*-statistic. For a 1-day event window, the *t*-statistic is the one-day residual return divided by the standard error of the regression residual returns. For multiday event windows, the *t*-statistic is the cumulative residual return over the event window divided by the product of the standard error of the regression residuals multiplied by the square-root of the number of trading days in the event window. In either case, if the absolute value of the *t*-statistic is greater than the critical *t*-statistic value (1.96 for large samples), the likelihood that the residual return could have been caused by random volatility alone is less than 5%, which is generally accepted to be so unlikely that the random volatility explanation can be rejected.

<sup>48</sup> The slight arithmetic discrepancy is due to rounding.



198. Since market and sector effects were controlled for, effects of information related to the New Monsanto business were eliminated, and the random volatility explanation was rejected, it follows that the price decline must have been caused by Company-specific news related to Pharmacia's pharmaceuticals business.
199. In addition to the three-day price decline being statistically significant, so are the price declines on February 7<sup>th</sup> and 8<sup>th</sup> when considered individually. These results are confirmation of the reliability and accuracy of my analysis.
200. On 7 February 2001, the Pharmacia Pharmaceutical Stock Price declined 3.15%. The Market Index declined 0.88%, and the Pharmaceutical Index rose 1.19%. According to the regression model, the Pharmacia Pharmaceutical Stock residual return that day was -4.17%. This is an unusually large one-day residual decline. With a *t*-statistic of -2.16, this residual return is statistically significant at the 3.1% significance level (p-value equals 0.031, confidence level is 96.9%).
201. The following day, 8 February 2001, the Pharmacia Pharmaceutical Stock Price declined 6.61%. The Market Index declined 0.65%, and the Pharmaceutical Index rose 0.43%. According to the regression model, the Pharmacia Pharmaceutical Stock residual return that day was -6.91%. This is an unusually large one-day residual decline in the Pharmacia Pharmaceutical Stock Price. With a *t*-statistic of -3.59, this residual return is statistically significant at the 0.04% significance level (p-value equals 0.0004, confidence level is 99.96%).<sup>49</sup>
202. That the residual returns on February 7<sup>th</sup> and February 8<sup>th</sup> each were statistically significant means that the magnitudes of the residual returns were so extreme that they could not reasonably have been caused by random volatility. By construction, the market factor, sector factor, and information related to the New Monsanto business were also eliminated as possible causes of the price declines. Therefore, each price decline must have been caused by Company-specific information about Pharmacia's pharmaceuticals business.
203. These event study results prove that there was a cause and effect relationship between the release of new material information and changes in the stock price – the essence of market efficiency.

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<sup>49</sup> The Pharmacia Pharmaceutical Stock Price declined \$0.75 on 6 February 2001. The residual decline was \$0.39, equivalent to 0.74%, which was not statistically significant.

Event Study Results: 6-8 August 2001

204. On Sunday, 5 August 2001, the *Washington Post* reported that the CLASS results presented in the *JAMA* article a year earlier were based on only six months of data, whereas the CLASS study actually had over a year's worth of data. The article noted that the *JAMA* publication and accompanying editorial were likely contributors to Celebrex's high sales. The Court of Appeals for the Third Circuit considered this event to be the final disclosure of the fraud and the end of the Class Period.<sup>50</sup>
205. Over the next three trading days, 6 August 2001 through 8 August 2001, the Pharmacia Pharmaceutical Stock Price rose 1.51%. The three-day cumulative residual return was 2.73%.
206. A residual return of 2.73% for the three-day period is a relatively modest price movement for the Pharmacia Pharmaceutical Stock Price. That residual return is associated with a *t*-statistic value of 0.82 (p-value equals 0.414), which indicates that the residual return over the three-day period following the news on 5 August 2001 was not statistically significant. The single-day returns on the Pharmacia Pharmaceutical Stock Price over the period 6-8 August 2001 were not individually significant either.
207. The lack of a statistically significant return following the news on 5 August 2001 is reasonable. Although this was the first public discussion suggesting that Defendants may have had the intent to mislead, the results of the complete CLASS study had been released to the market six months earlier along with the FDA Advisory Committee reports. In the interim, the market had already revalued Pharmacia stock to reflect the negative economic impact of the CLASS results.
208. Since only new valuation-relevant information should cause a stock price reaction in an efficient market, the lack of significant movement following this event is consistent with market efficiency.

**Event Study on Pharmacia Stock Returns without Removing New Monsanto**

209. While it is appropriate and correct to computationally remove New Monsanto from the Pharmacia stock price as in the event study described above, in order to determine whether

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<sup>50</sup> *Pharmacia*, 554 F.3d 342.

the event study results depend on this adjustment, I re-ran the event study on the actual Pharmacia stock prices and returns, which combine the New Monsanto business with the pharmaceuticals business.

210. In this alternate event study, I included two sector indexes in the regression model, one to account for Pharmacia's pharmaceuticals business and the other to account for its chemicals business. In its year 2000 Proxy, the Company similarly compared its performance to pharmaceutical peers and chemical industry peers.<sup>51</sup>
211. For the chemicals portion of Pharmacia's business, I used the S&P Chemicals Index ("Chemicals Index"). Among other constituents, the Chemicals Index includes E.I. DuPont de Nemours and Company ("DuPont") and Dow Chemical, which were specifically cited by Old Monsanto and New Monsanto as being peer companies.<sup>52</sup>
212. The index levels and returns of the Chemicals Index are presented in Exhibit-10.
213. I ran a regression modeling the return of Pharmacia stock as a function of: 1) a constant term, 2) the returns of the Market Index, 3) the returns of the Pharmaceutical Index, and 4) the returns of the Chemicals Index.
214. The regression was run on daily returns covering the period 19 October 2000 through 18 October 2001, the same estimation period used in the original event study. I again used dummy variables to control for 6-8 February 2001 and 6-8 August 2001.
215. The results of this estimation of the regression modeling of Pharmacia's stock returns are presented in Exhibit-11.
216. For the event dates, I computed the explained portion of the Pharmacia common stock return by adding: 1) the estimated regression intercept term, 2) the respective day's Market Index return multiplied by the Market Index coefficient estimated by the regression, 3) the Pharmaceutical Index return multiplied by the regression's Pharmaceutical Index coefficient, and 4) the Chemicals Index return multiplied by the regression's Chemicals Index coefficient.
217. The residual return for each date is the actual return minus the explained return.

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<sup>51</sup> Pharmacia Corporation – Form DEF 14A, filed 22 May 2000.

<sup>52</sup> Monsanto Corporation – Form DEF 14A, filed 15 March 1999; Monsanto Corporation – Form DEF 14A, filed 16 March 2001.

#### Results of Alternative Event Study

218. The results of the event study on the Pharmacia stock price inclusive of New Monsanto are presented in Exhibit-12.
219. As was the case with the Pharmacia Pharmaceutical Stock Price, the unadjusted Pharmacia stock price fell on each of the three days 6 February 2001 through 8 February 2001. The cumulative three-day decline in response to the corrective disclosure was statistically significant. The single-day declines on 7 February 2001 and 8 February 2001 were also individually statistically significant.
220. Again as before, there was no statistically significant return following the publication of the *Washington Post* article on 5 August 2001.
221. Regardless of the test specification, the corrective disclosure event that occurred 6-8 February 2001 caused the price of Pharmacia stock to fall significantly.

#### Market Efficiency Summary and Conclusion

222. Pharmacia stock traded on the NYSE where trading is facilitated by a specialist who is a lead market maker. The Company was widely covered by analysts and the news media. Institutional ownership of Pharmacia stock was widespread. Trading was active. Market capitalization and float were high. Current and historical financial information about the Company were readily available to investors and analysts. The stock's bid-ask spread was narrow. The event studies proved that there was a cause and effect relationship between the release of new material information and movements in the Pharmacia stock price.
223. Pharmacia stock satisfied the *Cammer* and *Krogman* factor tests that indicate market efficiency. The *DVI* Court had also adopted these indicators. It is particularly noteworthy that Pharmacia stock satisfied the empirical *Cammer* factor, which the *DVI* Court had emphasized, as this factor demonstrates the essence of market efficiency.
224. Given these facts, I conclude that Pharmacia common stock traded in an efficient market over the course of the Class Period.

## **LOSS CAUSATION**

225. Over the course of the Class Period, the alleged misrepresentations and omissions caused the price of Pharmacia stock to be artificially inflated. When the truth about the CLASS study emerged, the artificial inflation dissipated, causing the stock price to decline and investors to suffer losses.
226. These conclusions are based on a careful analysis of Defendants' statements, FDA reports, equity analyst reports, event study analysis focusing on the empirical reaction of the Pharmacia stock price to corrective disclosures, and analysis of potentially confounding information, as described next.

### **Company Statements Confirm the Materiality of the Alleged Misrepresentations and Omissions**

227. Both prior to and during the Class Period, the Company acknowledged the importance of Celebrex to Pharmacia as well as the importance of the CLASS trial to Celebrex's future growth prospects.
228. Given the importance of the Celebrex franchise to Pharmacia's financial performance, misrepresentations and omissions that overstate the economic potential of the product would also inflate the value of the Company.

### **Importance of Celebrex to Pharmacia**

229. Celebrex was the Company's largest product as measured by annual sales and was a strong contributor to Pharmacia's revenue and earnings growth. Celebrex represented 20.7% and 22.5% of Pharmacia's pharmaceuticals sales for the fiscal years 2000 and 2001, respectively.<sup>53</sup> For those same respective years, sales of Celebrex were 3.7 and 3.5 times greater than sales of Pharmacia's second best selling drug, Ambien.<sup>54</sup>
230. That Pharmacia recognized Celebrex's extreme importance to its business and future prospects is illustrated in the following:

“Sales growth in the first quarter was driven by a 14% increase in U.S. pharmaceutical sales led by Celebrex (celecoxib), the leading prescription

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<sup>53</sup> Pharmacia Corporation Form 10-K405 for the Fiscal Year Ended 31 December 2001, filed 5 March 2002, p. 32.

<sup>54</sup> *Ibid.*

arthritis medicine. Celebrex recorded sales of \$534 million in the quarter and has surpassed \$2 billion in total sales since its launch in the first quarter of 1999. ...Celebrex continues to gain sales after the best launch in pharmaceutical history. Physicians have now written more than 21 million prescriptions for Celebrex since its initial launch in the U.S. in 1999.”  
**“Pharmacia Corporation Reports 27% Increase in First-Quarter Earnings-Per-Share,” Company press release, *PR Newswire*, 25 April 2000.**

“[Alan Heller, Head of Searle Units, Pharmacia Corporation:] In the U.S. Celebrex continues to enjoy a substantial advantage versus Vioxx in refill rate, capsules per prescription, and average days of therapy per prescription meaning that every Celebrex new prescription leverages into substantially more sales for Pharmacia than Merck gets from a Vioxx new prescription.”  
**“Pharmacia Corporation First Quarter Earnings Release Conference Call,” 25 April 2000, Exhibit 336 at [DEFS 01221351].**

“Commenting on the company’s results, Pharmacia Chief Executive Officer Fred Hassan said: ‘Our performance this quarter was driven by solid contributions from both our pharmaceutical and agricultural businesses. In our pharmaceutical business, we remain pleased with the acceptance of Celebrex by patients and doctors, and our agricultural business continues to grow satisfactorily.’”  
**“Pharmacia Reports 18% Increase in Second Quarter Earnings per Share,” Company press release, *PR Newswire*, 25 July 2000.**

“Celebrex, the number one selling prescription arthritis medication worldwide had sales of \$630 million in the quarter and \$1.2 billion in the first half. Celebrex is being launched in several key European markets in the second half. Celebrex is now benefiting from cross-selling opportunities through the combined sales forces of the new company.”  
*Ibid.*

“[Fred Hassan, CEO:] As planned, the engines of this growth were our key global products, led by Celebrex. Carrie will talk in detail about our product performance so I’ll highlight just a few points. Regarding Celebrex, we continue to be pleased with the strong U.S. performance as well as the expanding international performance. Underlying the good numbers is a very positive response to Celebrex by physicians and by patients.”  
**“Pharmacia Teleconference: Second-Quarter Results and Outlook,” transcribed from audio obtained from Bloomberg, 25 July 2000.**

“[Carrie Cox, President of Global Business Management:] During the quarter, Celebrex clearly moved into the number one position as America’s most prescribed arthritis product, surpassing Ibuprofen, the

long-time gold standard. Our goal is for Celebrex to keep a firm hold on the number one position in the market.”

*Ibid.*

“Among Pharmacia’s many important innovations is Celebrex, the world’s leading prescription arthritis medicine.”

**“Pharmacia Corporation Reports 19% Increase in First-Quarter Earnings-Per-Share,”** Company press release, *PR Newswire*, 25 April 2001.

#### The Importance of CLASS to Celebrex

231. As Celebrex was highly important to Pharmacia, so the CLASS trial was highly important to Celebrex. If CLASS were to demonstrate improved GI safety over traditional NSAIDs, Celebrex could gain greater acceptance among managed care providers, which would boost the product’s sales.
232. Prior to Celebrex’s approval and its attaining blockbuster status, the Company anticipated that successful CLASS study results would likely lead to FDA removal of the GI warning on Celebrex’s label. Elimination of the warning was estimated to be worth approximately \$300 million in additional peak sales.

“It is estimated that such a study could contribute \$300 million change in peak sales based on:

- deletion of class warning
- participants in outcome studies have higher prescribing practices.”

**“Executive Summary: Celebra Life Cycle Plan 1998-1999 Budget,”** dated 21 June 1998, Exhibit-126 at [DEFS 01380798].

233. The following public statements made by the Company further indicate the importance that was placed on the CLASS trial and its results.

“[Fred Hassan, CEO:] I would just like to underscore some key highlights. With Celebrex, we now have exciting new data that shows that Celebrex has a truly exceptional safety profile. This makes us feel good at a time when other products have been affected by safety concerns.”

**“Pharmacia Corporation First Quarter Earnings Release Conference Call,”** 25 April 2000, Exhibit 336 at [DEFS 01221348].

“[Alan Heller, Head of Searle Units, Pharmacia Corporation:] In addition to our European launches, another major growth driver will be the Celebrex long-term safety outcome study. The data presented to date is top line and first cut, but already a powerful story has emerged. ... The top

line take-away is that our landmark long-term arthritis study provides compelling evidence of the broad safety profile of Celebrex across a full spectrum of GI measures and in major organ systems versus the traditional NSAID comparators ibuprofen and dyclofenac.”

*Ibid.*, at [DEFS 01221352].

“[Fred Hassan, CEO:] As you may remember, we had mentioned that there are five engines of growth that will add \$4.5 billion in sales over the next three years. These five engines being Celebrex, Xalatan, Detrol, Camptosar and Zyvox. ... We are also very pleased with the CLASS data which has now come out for Celebrex and the European approval of Celebrex.”

*Ibid.*, at [DEFS 01221357].

“[Fred Hassan, CEO:] As a result of the new data that’s coming out from Searle, as well as from Merck, we believe that the market is poised for major expansion over the next three or four years. And it will become very difficult for managed care to prevent access to these products, especially when you look at figures like 2 pints of blood loss with the older NSAIDs.”

*Ibid.*, at [DEFS 01221358].

“[Alan Heller, Head of Searle Units, Pharmacia Corporation:] Well, the only thing that I might add to that is that you have to recognize that something like 65% of the marketplace is still in the traditional NSAIDs. I think the strength of the data that we’re showing, particularly with our outcome study, really speak to not only perhaps confirming some of the known dangers of the traditional NSAIDs but also points out some new and unexpected dangers such as the blood loss. That’s really going to be a powerful tool for us to penetrate that 65% of the business. I share Fred’s confidence that some of the flatness in the prescriptions growth rate you saw in the first quarter will definitely be accelerating going forward.”

*Ibid.*, at [DEFS 01221358].

“[Alan Heller, Head of Searle Units, Pharmacia Corporation:] I obviously can’t speak to the Vioxx label change, if they will get one at all, but our expectations is to have our sNDA filed before the end of the second quarter. And I think that the data is so significantly compelling to request from the FDA that they look at it on an expedited basis.”

*Ibid.*, at [DEFS 01221358].

“[Carrie Cox, President of Global Business Management:] Based on the efficacy and safety data from the CLASS, VIGOR, and recent head-to-head trials, we are more convinced than ever that Celebrex is a superior product to Vioxx with equal efficacy and a better safety profile. Celebrex



can also be used at higher doses for the severe pain of rheumatoid arthritis because there are no dose limiting safety issues. Moving forward, we plan to leverage the range of strong new data on Celebrex to create even more powerful support and momentum for the continuing conversion of traditional NSAIDs to Celebrex prescriptions.”

**“Pharmacia Teleconference: Second-Quarter Results and Outlook,” transcribed from audio obtained from Bloomberg, 25 July 2000.**

“[Carrie Cox, President of Global Business Management:] So, there is significant growth opportunities still there. We are, in fact, expecting growth in all major markets, next year, including the US. As you know, the long-term data is now available through publication. It has been submitted to the FDA for consideration. There is a significant data stream of new information coming to support the very strong profile of Celebrex both now for the rest of this year and coming into next year.”

**“Pharmacia Teleconference: Third-Quarter Results and Outlook,” transcribed from audio obtained from Bloomberg, 30 October 2000.**

“[Carrie Cox, President of Global Business Management:] In terms of the situation for Celebrex moving forward, the *JAMA* paper, as mentioned, was published in September, and that contains the results from the long-term outcomes studies. I think we’ve had lot of benefit in the marketplace of being able to use the data.”

**“Pharmacia Corporation 4Q 2000 Conference Call, 12 February 2001,” Exhibit-401 at [DEFS-01221430 - DEFS-01221431].**

234. As the above excerpts indicate, Defendants acknowledged that Celebrex was an important driver of the Company’s sales and growth, and the CLASS study results were an important factor in promoting Celebrex’s success.

#### **Analysts and the Financial Media Deemed the Alleged Misinformation Material**

235. Investment analysts and the financial press understood and commented on the importance of Celebrex to Pharmacia and the importance to Celebrex of the CLASS trial.

#### **Analysts Considered Celebrex Important to Pharmacia**

236. As is evident in the following excerpts from analyst reports published prior to and during the Class Period, analysts covering Pharmacia viewed Celebrex as highly important to Pharmacia’s business and valuation:

“Pharmaceutical earnings were propelled by the highly successful Celebrex, as expected, with EBIT jumping \$42 million (23%) to \$223 million, even with partnering down year-to-year.”

**“Fourth Quarter Earnings on Target,”** by William R. Young and Nancy F. Traub, Donaldson, Lufkin & Jenrette, analyst report, 11 February 2000, p. 1.

“Pharmacia & Upjohn’s board might have looked at Monsanto principally for its recently launched blockbuster product Celebrex. If anything had been noticeably absent from the Pharmacia & Upjohn product line, it was a blockbuster.”

**“A Comprehensive, Step-by-Step Analysis Going into the Merger with Pharmacia & Upjohn,”** by Andrew Cash, *et al.*, PaineWebber, analyst report, 16 March 2000, p. 8.

“Celebrex Franchise: Shifting Into Overdrive. Simply put, Celebrex proved to be the single most successful new product launch in the history of the pharmaceutical industry, and it exceeded everyone’s expectations.”

**“Creation of New ‘Porsche Pharma’ Offers Potential To Be Better Than Biotech,”** by Richard Stover, Arnhold & Bleichroeder, Inc., analyst report, 22 March 2000, p. 15.

“Monsanto’s Coxib Franchise Drives 40-45% Of Pharmacia’s Revenue Growth.”

**“Pharmacia Corp. Starts Trading Today – Great Prospects on Tap,”** by Ian Sanderson, *et al.*, SG Cowen, analyst report, 3 April 2000, p. 2.

“Celebrex, the COX-II inhibitor for the treatment of osteoarthritis and rheumatoid arthritis, is the crown jewel of Searle and remains the most important product in the Pharmacia portfolio.”

**“Initiating Coverage with an Outperform Rating,”** by Jami Rubin, *et al.*, Morgan Stanley Dean Witter, analyst report, 4 April 2000, p. 5.

“Additionally, Celebrex’s rapid ascent to a \$2+ billion product this year (just two years post launch), should significantly boost cash flow, impacting the EPS line.”

**“1Q00 EPS; Concerns over Top Line,”** by Mara Goldstein and Steven B. Gerber, CIBC World Markets, analyst report, 25 April 2000, p. 1.

“Newer products continue to drive growth – Celebrex, the market leading antiarthritic, co-promoted with Pfizer, recorded worldwide revenue of \$534 million (up 92%) in 1Q00.”

**“1Q00 EPS In Line; Sales Disappointing with Just Modest Growth,”** by Jeffrey Chaffkin, *et al.*, PaineWebber, analyst report, 26 April 2000, p. 2.

“The Cox-II franchise, which includes Celebrex, remains the most important franchise for Pharmacia.”

**“PHA Power Brunch with Dr. Goran Ando,”** by Jami Rubin, *et al.*, Morgan Stanley Dean Witter, analyst report, 30 May 2000, p. 2.

“Celebrex and the follow-up compounds that should sustain Pharmacia’s COX-2 group of drugs beyond 2001 are expected to become a multi-billion dollar franchise able to support the company growth for at least the next five years.”

**“Initiating with a Strong Buy; A Blue Chip in the Making,”** by Sergio Traversa and Sena P. Lund, ING Barings, analyst report, 21 July 2000, p. 1.

“U.S Pharmaceuticals sales jumped 26% in Q2, to \$1,710MM, aided by \$548MM (+92%) of Celebrex sales.”

**“Ag. Products a Big Surprise (Positive) in Q2 – EPS on Target,”** by Ian Sanderson, *et al.*, SG Cowen, analyst report, 25 July 2000, p. 1.

“Pharmacia is benefiting from increasing sales of painkiller Celebrex.”

**“Initiating Coverage on Pharmacia Corp.,”** by Mike Krensavage and Michael Hearl, Raymond James & Associates, analyst report, 8 November 2000, p. 8.

“Pharmaceuticals is the main driver, with sales growth potential in the mid-teens this year and next, driven largely by Celebrex.”

**“PHA – Monsanto Provides Transparency on Rx Value,”** by Jami Rubin and Mark Wiltamuth, Morgan Stanley Dean Witter, analyst report, 16 November 2000, p. 1.

“Pharmacia is a compelling growth story driven by: the success of the blockbuster Celebrex.”

**“A Solid Product-Driven Growth Story,”** by Sergio Traversa and Sena P. Lund, ING Barings, analyst report, 17 November 2000, p. 1.

#### The Financial Press Reported on the Importance of Celebrex

237. The financial press understood and reported the importance of Celebrex to Pharmacia’s business, as is evident in the following quotes published prior to and during the Class Period:

“S&P also said that many of Monsanto’s product lines enjoy above-average profitability and solid cash flow generation. It said Monsanto’s G.D. Searle pharmaceuticals unit has staged a good profit recovery in recent years, led by the successful launch of its COX-2 drug, Celebrex, in early 1999.”

**“Pharmacia & Upjohn on S&P Watch-Negative,”** *Dow Jones Newswires*, 20 December 1999.

“Saks said Pharmacia would win immediate prominence by obtaining Monsanto’s hot-selling Celebrex, which he expects to generate annual sales of over \$3 billion by 2002.”

**“Focus-Monsanto, Pharmacia & Upjohn Agree to Merge,”** by Emily Kaiser, *Reuters News*, 20 December 1999.

“After Monsanto developed Celebrex, executives decided that Searle’s sales force was too small to realize the arthritis drug’s full potential. They formed a partnership with Pfizer Inc., a larger drug company, to market Celebrex. Even so, Celebrex’s success was enough to turn Searle from an underperformer to a star. Many Wall Street analysts were urging Monsanto to jettison the drug business a few years ago. They now say it’s the most attractive part of the company.”

**“Monsanto, Pharmacia Will Merge,”** by David Nicklaus, *St. Louis Post-Dispatch*, 20 December 1999.

“Searle and Pfizer Inc. reported that Celebrex (celecoxib capsules) in its first year generated an unprecedented 19 M prescriptions, a volume unrivalled by any other prescription drug in its first year. In fact, Celebrex prescriptions now rival generic ibuprofen, the long-established leader in the arthritis market. Further, new prescriptions of Celebrex exceeded those of the next two leading blockbusters combined, Viagra (sildenafil citrate) and Lipitor (atorvastatin calcium), during the same post-launch period.”

**“Celebrex at One Year – Helping Many Return to Daily Activities,”** *Factiva Press Release Service*, 29 February 2000.

“The company said sales growth in the first quarter was driven by a 14% increase in U.S. pharmaceutical sales led by Celebrex, an arthritis medicine.”

**“Pharmacia Corp. 1st Quarter Operating Net 33 Cents a Diluted Share Vs 26 Cents,”** *Dow Jones Newswires*, 25 April 2000.

“Analysts agreed that Celebrex, the COX-2 inhibitor for treating osteoarthritis and rheumatoid arthritis, is the key driver for Pharmacia.”

**“Pharmacia Posts Profit Growth Despite Slower Sales Rise,”** by Beth M. Mantz, *Dow Jones Newswires*, 25 April 2000.

“The company’s main earnings driver was a 92 per cent increase in sales of its anti-arthritic drug Celebrex.”

**“Pharmacia Posts 27% First-Quarter Rise,”** by Adrian Michaels, *Financial Times*, 26 April 2000.

“‘I don’t think he was forced out, because he did a great job with Celebrex - which is by far the most important drug in the combined organization,’ [Ian] Sanderson [SG Cowen pharmaceuticals analysts] said.”  
“**Pharmacia Says Former Monsanto Exec De Schutter to Retire,**” *Reuters News*, 4 May 2000.

“Pharmacia boasts one of the strongest profit growth outlooks of any major drug company, owing in part to Monsanto’s Celebrex, the popular painkiller.”  
“**Microsoft Ruling Fails To Deter Further Tech Gains,**” by Andrew Bary, *Barron’s*, 12 June 2000.

“SG Cowen analyst Ian Sanderson raised his rating on drug company Pharmacia Corp. to strong buy from buy on Friday. ... [C]alled Pharmacia ‘a top pick.’ ... ‘Competitive position of the Celebrex/Valdecobix franchise looks solid.’”  
“**Research Alert-SG Cowen Ups Pharmacia,**” *Reuters News*, 4 August 2000.

“The accounting issue seems it will translate to higher expense levels in the future, said ABN AMRO analyst Mario Corso, citing that the milestones now were being used to offset sales and marketing expenses and research and development costs. But ‘with big products like Celebrex ... those payments aren’t too much of a concern,’ he added.”  
“**Pharmacia 3rd Quarter Earns Story Overtaken by Co Future Guidance,**” by Beth M. Mantz, *Dow Jones Newswires*, 30 October 2000.

“Pharmacia’s previous offering in this class is Celebrex, its largest-selling drug.”  
“**Pharmacia Files for Pain Drug FDA Approval,**” *Reuters News*, 30 October 2000.

“Celebrex is hugely important to Pfizer, of New York, and Pharmacia, of Peapack, N.J. Celebrex had one of the most successful drug launches ever; sales for the first three quarters of this year exceeded \$1.8 billion.”  
“**Pharmacia Corp., Pfizer Are Warned on Celebrex Ads,**” by Chris Adams, *Wall Street Journal*, 12 December 2000.

“Industry analysts expect its best-selling COX-2 drug Celebrex to help drive strong fourth-quarter growth when the firm reports on February 12.”  
“**Davos-Pharmacia Seeks Acquisitions in Cancer Field,**” by Ben Hirschler, *Reuters News*, 28 January 2001.

#### Analysts Considered CLASS Important to Celebrex

238. The following statements from analyst reports published prior to and during the Class Period demonstrate that analysts covering Pharmacia regarded the CLASS trial as a very

positive development for Celebrex. Moreover, analysts apparently accepted Defendants' representations and remained uninformed about the alleged omissions.

"Dr. Needleman [Co-President and Chief Scientist of Monsanto] stated that the 'next big thing' for Celebrex is likely to be the submission of the long-term clinical outcome data. The data is currently being analyzed and the sNDA could be filed during the first half of this year. According to Dr. Needleman, these studies are being conducted in hopes that they will lead to a meaningful label revision - with the best case being a removal of the standard NSAID warning on gastrointestinal events from Celebrex's label."

**"Summary of Comments by Phil Needleman," by Jami Rubin, et al., Morgan Stanley Dean Witter, analyst report, 31 January 2000, p. 3.**

"The imminent completion of the CLASS study, conducted to demonstrate a reduction in the incidence of severe GI side effects of ulcers and bleeds, should result in a supplemental filing to remove the NSAID class warning from the label. ***This should prove to be the single most important event driving the expansion of the COX-2 inhibitors to a dominant position in arthritis treatment.*** Further, the CLASS study evaluated the 800mg. dose (twice the maximum approved arthritis dose) which should add to expanding clinical evidence that Celebrex causes no dose-related increase in side effects.

...

In the final analysis, Celebrex is still very early in its life cycle and removal of the traditional NSAID class warnings from approved labeling should catapult the COX-2's to a dominant position in the prescription NSAID market. Further we believe, it will provide the ammunition for effective direct-to-consumer advertising to cannibalize much more rapidly on OTC NSAIDs and expand the prescription segment of the market."

**"Creation of New 'Porsche Pharma' Offers Potential To Be Better Than Biotech," by Richard Stover, Arnhold & Bleichroeder, Inc., analyst report, 22 March 2000, p. 16 (emphasis added).**

"More significant Celebrex-related catalysts are slated for 2000. The next big thing in the Celebrex story should take place around midyear, when the companies are expected to submit a supplemental NDA (sNDA) with the results of their outcomes trial (the CLASS trial). These trials compare the incidence of serious gastrointestinal side effects (such as perforations, ulcers, and GI bleeds) experienced by patients on Celebrex versus traditional nonsteroidal anti-inflammatory drugs (NSAIDs). The objective in submitting these trials is to persuade the FDA to revise the label on Celebrex, which currently includes the standard NSAID warning.

Removal, or even significant revision, of this warning would likely have a major positive impact on reimbursement practices and sales of the product.”

**“Initiating Coverage with an Outperform Rating,”** by Jami Rubin, *et al.*, Morgan Stanley Dean Witter, analyst report, 4 April 2000, p. 5 (emphasis added).

“‘The data was extremely positive,’ said Barbara Ryan, a drug industry analyst at BT Alex. Brown, adding that it confirmed what had been presented from earlier, shorter-term studies. The real issue, she said, was whether the drug companies could convince the FDA to change the Celebrex labeling to indicate that it was safer than nonsteroidal anti-inflammatory drugs (NSAIDs).”

**“Update 1-Long-Term Data Show New Arthritis Drug Safer,”** by Kathy Fieweger, *Reuters News*, 17 April 2000.

“On Monday before the market opened, PHA and PFE (\$38) announced positive results of their eagerly anticipated CLASS study. ... In most respects, the study served its purpose of differentiating the long-term safety profile of Celebrex from NSAIDs.”

**“Positive Results of Celebrex CLASS Trial Released,”** by Jami Rubin, *et al.*, Morgan Stanley Dean Witter, analyst report, 18 April 2000, p. 2.

“PHA and PFE plan to submit these data to the FDA in hopes of revising (or best case, removing) the standard NSAID warning about GI events that currently appears in the label. A revision of the label is likely to have a positive impact on reimbursement and sales of Celebrex.”

*Ibid.*

“[W]e continue to believe that Celebrex will show impressive growth during the coming quarters, fuelled by new research data.”

**“Ready for a Pick-Up Later This Year!,”** by Peter Sellei and Kristofer Liljeberg-Svensson, Carnegie, analyst report, 25 April 2000, p. 3.

“We believe that Celebrex offers potential upside to PHA’s stock price. ... PHA will expand upon the recently announced GI safety data with a more complete presentation at the Digestive Disease Week Conference May 21-24. This data is expected to show much lower incidence of GI complications than traditional NSAID’s, and an FDA filing this quarter could remove the NSAID warning label as soon as late 2000. This occurrence would open the door for more widespread usage at managed care facilities.”

**“Celebrex Poised to Bounce; AG Weakness Less Important,”** ABN AMRO, analyst report, by Maria Corso and Scott Henry, 25 April 2000, p. 2.

“Several significant Celebrex-related catalysts are slated for 2000. The ‘next big thing’ in the Celebrex story should take place around mid-year,



when PHA and PFE are expected to submit a supplemental NDA (sNDA) with the results of their outcomes trial (the CLASS trial). ...The objective in submitting these trials to the FDA is to convince the agency to revise the label on Celebrex, which currently includes the standard NSAID warning. Removal, or even significant revision, of this warning would likely have a major positive impact on reimbursement practices and sales of the product.”

**“Ag Off to a Slow Start, but 2000 EPS in Tact,” by Jami Rubin, *et al.*, Morgan Stanley Dean Witter, analyst report, 26 April 2000, p. 3.**

“We believe the long-term safety data generated by the CLASS (Celebrex) and VIGOR (Merck’s Vioxx) trials will re-accelerate the coxibs’ penetration of the NSAID market by removing the NSAID side effects warning label. Pharmacia plans to file the CLASS data this quarter, with an FDA-approved label modification possible by late this year.”

**“Ag. Franchise in a Q1 Drought: Pharma Will Pick Up the Slack,” by Ian Sanderson, *et al.*, SG Cowen, analyst report, 26 April 2000, p. 2.**

“The two COX-2 drugs (including MRK’s Vioxx) should capture a significant share of the anti-arthritic market, reflecting the increasing awareness that these agents cause far fewer GI problems than the older NSAIDs. Should the FDA accept the results of recently completed safety studies that PHA and MRK have conducted on their respective products, the warning labels of Celebrex and Vioxx could be softened somewhat. In our opinion, the odds of such a development in 2H’00 are about 50/50. Such a labeling change would obviously have a favorable effect on the sales of both products, and could make our Celebrex domestic revenue forecast somewhat conservative.”

**“2Q Pharma Sales To Show Accelerated Growth,” by Kent Blair, *et al.*, Donaldson, Lufkin & Jenrette, analyst report, 12 June 2000, p. 3.**

“A key going forward will be to see how the FDA views the new safety and whether or not it is rewarded with a meaningful label change.”

**“Prospects for Growth,” by Jeffrey Chaffkin, *et al.*, PaineWebber, analyst report, 6 July 2000, p. 4.**

“We believe that Celebrex will continue to show impressive growth during the coming quarters, fuelled by new research data and its launch in major European markets.”

**“Impressive Top-Line Growth!,” by Peter Sellei and Kristofer Liljeberg-Svensson, Carnegie, analyst report, 25 July 2000, p. 1.**

“There remains huge market expansion potential for Celebrex and Merck’s Vioxx, as 60% of arthritis pain patients still are on traditional NSAIDs. We believe the long-term safety data generated by the CLASS (Celebrex) and VIGOR (Merck’s Vioxx) trials may accelerate the coxibs’



penetration of the NSAID market by removing the NSAID adverse events warning label.”

“H2 Earnings Growth Acceleration on Tap Post a Convincing Q2,” by Ian Sanderson, *et al.*, SG Cowen, analyst report, 26 July 2000, p. 2.

“Sometime in ‘01, the FDA is expected to relax the side effect warnings on Celebrex and Vioxx. Those moves should further enhance the COX-2s’ share of the overall anti-arthritic market.”

“Strong Volume Gains and Synergies To Fuel Rapid EPS Growth,” by Kent Blair, *et al.*, Donaldson, Lufkin & Jenrette, analyst report, 23 August 2000, p. 1.

“Our Q3(00) forecasts indicate impressive growth for Celebrex, fuelled by numerous research data indicating that COX-2 inhibitors are superior to the older class of drugs, the so-called NSAID’s, and that the COX-2 inhibitors might be prescribed for new indications.”

“9M(00) Previews,” by Peter Sellei and Kristofer Liljeberg-Svensson, Carnegie, analyst report, 26 October 2000, p. 1.

“While this marketing and positioning battle will continue to rage, we believe the longer-term opportunity for the COX-2 class will be the potential removal of gastrointestinal warning labels that appear on both Celebrex and Vioxx labeling, a consideration that would lead to another significant growth leg to the class.”

“Uniquely Positioned Pharmaceutical Growth Platforms,” by Kenneth Kulju, *et al.*, Credit Suisse First Boston, analyst report, 5 December 2000, p. 8.

“These labeling revisions will also be important in driving prescription conversion with larger managed care accounts.”

“4Q Preview,” by Kenneth Kulju, *et al.*, Credit Suisse First Boston, analyst report, 5 January 2001, p. 1.

“We believe the label improvements resulting from the long-term safety data generated by the CLASS (Celebrex) and VIGOR (Vioxx) studies, should support growth beginning in H2:2001.”

“Pharmacia Corporation,” Steve Scala, *et al.*, SG Cowen, analyst report, 11 January 2001, p. 2.

#### The Financial Press Reported on the Importance of CLASS

239. As is evident in the following excerpts from the financial media published during the Class Period, the CLASS trial was considered to be highly important to Celebrex:

“No previous study has examined such a broad range of (gastrointestinal - GI) side effects - which encompass events ranging from serious and often devastating GI ulcers and ulcer complications, to silent but medically

important damage to the lining of the intestine, to symptoms like abdominal pain,’ said Lee Simon, a professor at Harvard Medical School. ‘I’m incredibly excited about this data set,’ he added. ‘These drugs are just basically safer.’”

**“Update 1-Long-Term Data Show New Arthritis Drug Safer,” by Kathy Fieweger, *Reuters News*, 17 April 2000.**

“Two new rival arthritis drugs that have already become blockbusters, Merck & Co.’s Vioxx and Pharmacia Corp.’s Celebrex, aim to propel sales into higher orbit by convincing U.S. regulators in coming months that their medicines are far safer than standard treatments. A key step in that campaign comes this week, when the firms will unveil data from separate clinical trials they say prove their medicines are overwhelmingly safer than older ulcer-causing arthritis remedies known as nonsteroidal anti-inflammatory drugs (NSAIDs).”

**“Vioxx, Celebrex Aim To Profit from Improved Safety Labels,” by Ransdell Pierson, *Reuters News*, 22 May 2000.**

“The problem arises from the labeling for both Vioxx and Celebrex. The label alludes to the need for these long-term safety studies about gastrointestinal effects because only those side effects occurring with NSAIDs are known. ‘If the GI (gastrointestinal) warning section on the label were removed, it would greatly help these drugs in further penetrating the NSAID market,’ said Ryan Beck Southeast Research analyst Neil Sweig.”

**“Safety Data May Not Affect Who Leads Arthritis Market,” by Beth M. Mantz, *Dow Jones Newswires*, 24 May 2000.**

### **The Court Concluded that the CLASS Results and Related Statements Were Material**

240. In its Memorandum Opinion dated 22 January 2007, the Court concluded that the CLASS results and the 17 April 2000 press release about the CLASS results were material information.

“Given the weight attached to CLASS results by Defendants and various stock analysts, and the fact that CLASS was widely reported in the financial and mainstream media, the Court finds the statements cited by Plaintiffs, including Defendants’ April 17 press release ... to be material.” *Alaska Electrical Pension Fund v. Pharmacia Corp.*, No. 03-01519 (AET), 2007 U.S. Dist. Lexis 5410, at \*7-\*8 (D.N.J. January 22, 2007).

241. Not only did the Court find the initial release of the incomplete CLASS results to be a material event, but the Court concluded that the FDA’s data release and the Advisory

Committee's decision not to recommend a label change, on 6-7 February 2001, constituted a "curative disclosure" event that caused the Pharmacia stock price to decline:

"The Court finds that the FDA's data release and the advisory committee ruling ('FDA Release') constituted a curative disclosure as they were substantial, widely-reported, and contradicted the Defendants' conclusions about the results of CLASS. ... Further, it is uncontested that this regulatory action caused a precipitous drop in Pharmacia's common stock price, which is evidence of its curative effect."

*Pharmacia*, 2007 U.S. Dist. Lexis 5410, at \*13.

242. As such, the Court determined that the disclosed information was material and its prior concealment had caused the stock price to be inflated.

243. Furthermore, the Court of Appeals for the Third Circuit concurred that alleged misrepresentations were material and caused the Pharmacia stock price to be inflated, and that the corrective disclosure in February 2001 caused the stock price to decline:

"And, of course, the materiality of the alleged misrepresentations is self-evident when we look at the market's negative reaction – to the tune of a nine-percent drop in stock price in three days – when defendants' analysis of the CLASS study was questioned in February 2001."

*Pharmacia*, 554 F.3d at 352.

244. The Court's findings are consistent with statements made by Defendants during the Class Period, and by analysts and the financial press. The facts of this case indicate that the alleged misrepresentations and omissions artificially inflated the price of Pharmacia stock. The disclosure event of February 2001 was a curative disclosure that caused the artificial inflation to dissipate, resulting in investor losses. Therefore, the alleged misrepresentations and omissions caused investor losses.

### **EMPIRICAL CONFIRMATION OF LOSS CAUSATION**

245. The significant decline in the Pharmacia Pharmaceutical Stock Price (and in the unadjusted Pharmacia stock price) on 6-8 February 2001, in reaction to the corrective disclosures, empirically confirms the materiality of the misrepresentations and omissions. This empirical result, coupled with an analysis of potentially confounding information, proves

that the misrepresentations and omissions had artificially inflated the price of Pharmacia stock during the Class Period and that, when corrected, they caused investors to suffer losses.

### **Events of 6-8 February 2001**

#### **The Corrective Disclosure**

246. As described above, prior to the 7 February 2001 FDA's Arthritis Advisory Committee meeting, on or about 6 February 2001, reports written by FDA reviewers that contained and analyzed CLASS data from the entire study were posted on the FDA's website. The new information provided to the market was voluminous and complex scientific, medical, and statistical information, but corrected Defendants' prior false or misleading statements about the CLASS study.
247. Late in the afternoon on 7 February 2001, the Advisory Committee stated that the full CLASS trial results indicated no significant GI safety advantage of Celebrex over traditional NSAIDs. As a result, the Committee did not recommend that the FDA approve a label change with respect to GI safety.
248. Reportage and commentary about the disclosure by medical professionals, the financial press, and analysts were extensive – continuing after the close of trading on 7 February 2001 and carrying over to 8 February 2001.
249. For example, in a report titled "CLASS Flunks Out," published on February 8<sup>th</sup>, CIBC analysts wrote that Pharmacia's stock price declined on 7 February 2001 on concerns that Celebrex's growth would stagnate without the label change and noted the potential for additional share price weakness on 8 February 2001.<sup>55</sup> After the close of trading on February 7<sup>th</sup>, Salomon Smith Barney analysts issued a report stating that the CLASS results would slow the growth of COX-2 inhibitors.<sup>56</sup>
250. The information about the CLASS study that was provided by the FDA reviewers and subsequently disseminated by news and analyst coverage was precisely the information that Defendants had been concealing throughout the Class Period. The market now knew the

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<sup>55</sup> "CLASS Flunks Out," by Mara Goldstein, Steven Gerber, M.D. and Adam Sohn, CIBC, analyst report, 8 February 2001.

<sup>56</sup> "PHA: FDA Reviews Celebrex & Vioxx Safety Data," by Mark Striker and George Grofik, Salomon Smith Barney, analyst report, 7 February 2001.

facts described above in paragraph 45. Consequently, the events of 6-8 February 2001 clearly constituted a corrective disclosure.

#### The Corrective Disclosure Dissipated Artificial Inflation

251. Over the three-day period, 6-8 February 2001, the residual decline in the Pharmacia Pharmaceutical Stock Price was a statistically significant \$5.92 per share, or 11.81% on a logarithmic return basis. This residual return controls for the market effect, the pharmaceutical sector effect, and any information related to the New Monsanto business. Moreover, the residual decline was too great to be attributable to random volatility. Therefore, the loss in value must have been caused by Company-specific information related to the pharmaceuticals business.
252. The three-day decline in the unadjusted Pharmacia stock price (*i.e.*, without removing New Monsanto) is statistically significant as well, proving that the result is robust to event study design.
253. The single-day residual Pharmacia Pharmaceutical Stock Price declines were also individually statistically significant on February 7<sup>th</sup> and 8<sup>th</sup>. The decline was 4.17% on February 7<sup>th</sup> and 6.91% on February 8<sup>th</sup>, equivalent to declines of \$2.14 per share and \$3.39 per share, respectively.
254. These single-day declines are also statistically significant in the event study conducted on the unadjusted Pharmacia stock price, proving that the results are robust to event study design.
255. That the single-day and cumulative residual returns were statistically significant indicates that the Company-specific news that emerged at this time caused the price decline.

#### Accounting for Potentially Confounding Information

256. To determine whether any information other than the CLASS disclosure contributed to the 6-8 February residual stock price decline, I examined all other Company-related news that emerged over those days and assessed the valuation effect, if any, of that potentially confounding information.
257. Four additional pieces of Company-specific information transpired on 6-8 February 2001:

- i. On 6 February 2001, Pharmacia announced that its drug Xalatan had become the top-selling treatment for open-angle glaucoma in Japan and that it had launched Zyvox in the U.K. Pharmacia also submitted an application for Somavert (a treatment for acromegaly).<sup>57</sup>
- ii. Also on 6 February 2001, Nycomed Amersham plc announced that it would proceed with an IPO of its life sciences unit, APBiotech.<sup>58</sup> Pharmacia owned 45% of APBiotech.<sup>59</sup>
- iii. After the close of trading on 6 February 2001, news emerged that Pharmacia had initiated a lawsuit against Alcon Laboratories for patent infringement regarding the manufacturing of Xalatan.<sup>60</sup>
- iv. After the close of trading that same day, the FDA posted a warning issued to Pharmacia about downplaying the risks of using Celebrex in conjunction with Coumadin (an anticoagulant). The FDA letter noted that this was the fourth letter dealing with Coumadin in Pharmacia's promotional materials for Celebrex.<sup>61</sup>

258. I analyzed each of these news items to determine whether or not they constituted new valuation-relevant information that may have contributed to Pharmacia's stock price decline beginning on 6 February 2001.

#### Xalatan Sales and Somavert Application Announcements

259. Pharmacia's announcement about Xalatan at the Merrill Lynch Global Pharmaceutical, Medical Device, and Biotechnology Conference did not include any quantitative information about the current level or projected growth of Xalatan sales. Therefore, it was unlikely that investors could have gleaned sufficient information from the announcement to change their assessment of Pharmacia's value.
260. Moreover, to the extent that the announcement did provide valuation-relevant information, it would have had a positive influence on Pharmacia's stock returns. This effect would have slightly reduced the overall stock price decline, offsetting the decline caused by the release

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<sup>57</sup> "Pharmacia's Xalatan Becomes the Number-One Selling Glaucoma Treatment in Japan," Company press release, *PR Newswire*, 6 February 2001.

<sup>58</sup> "Nycomed Pushes Ahead With Life Science IPO," *Reuters News*, 6 February 2001.

<sup>59</sup> Pharmacia Corporation Form 10-K for the Year Ended December 31, 2000, filed 25 March 2001, p. 8.

<sup>60</sup> "Pharmacia Sues Alcon over Patent for Glaucoma Drug," *Reuters News*, 6 February 2001.

<sup>61</sup> "Pharmacia Again Warned about Celebrex Promotion," by Lisa Richwine, *Reuters News*, 6 February 2001.

of the CLASS data. The news about the Somavert application submission was similarly positive.

261. Factoring in the countervailing positive price impact of this news, if any, would indicate that the valuation impact of the CLASS disclosure was even more negative than the net effect observed. I conservatively elected to assume there was no such offsetting price impact from the positive Xalatan and Somavert news.

#### APBiotech IPO

262. The news of Nycomed Amersham's plan to proceed with an IPO of APBiotech informed the market that Pharmacia's previously unmarketable asset, *i.e.* its 45% stake in the company, would become marketable. Since marketability enhances the value of an asset, this development, too, was positive.
263. Moreover, Pharmacia's 2000 Form 10-K mentioned APBiotech only once, indicating that it was not a major component of Pharmacia's business.
264. To the extent that the APBiotech announcement did provide any valuation-relevant information, it would likely have had a positive influence on Pharmacia's returns, thus slightly offsetting the decline caused by the CLASS data release. Accounting for the countervailing positive price impact of this development, if any, would indicate that the valuation impact of the CLASS disclosure was even more negative than the net effect observed. I conservatively elected to assume that the APBiotech IPO news caused no such offsetting price impact.

#### Alcon Laboratories Patent Lawsuit

265. News of Pharmacia's Xalatan patent infringement suit against Alcon Laboratories can be viewed as either a positive or negative. The suit could potentially have signaled that Pharmacia was concerned about the potential impact on Xalatan's sales of the competing drug, Travatan. Alternatively, if the market was already accounting for the potential impact of Travatan's launch, the lawsuit could be viewed as a positive, as the suit could either result in monetary compensation or a delay in Travatan's launch, both of which would benefit Pharmacia.
266. I searched analyst reports and news articles for commentary about the lawsuit. Other than one *Reuters* article, there was no additional news coverage or analyst commentary. I

therefore determined that the news of the lawsuit was considered too minor to have a meaningful impact on the valuation of Pharmacia's stock.

FDA Warning Letter about Celebrex and Coumadin Combination

267. After the close of trading on 6 February 2001, the FDA posted on its website a fourth warning to Pharmacia for downplaying the risks associated with concurrent use of Celebrex and Coumadin, an anticoagulant known generically as warfarin.<sup>62</sup> Specifically, the FDA's warning cited five audio conferences given by Dr. McMillen, on behalf of the Company, in March and May of 2000.
268. Two of the FDA's previous three warnings, issued in October 1999 and April 2000, involved promotional materials distributed by the Company. The third warning concerned a television ad and was issued in November of 2000.<sup>63</sup>
269. Potential complications arising from the interaction of Celebrex and Coumadin was not new information. In fact, the FDA had previously required the Company to add this information to the "Precautions" section of the Celebrex label as a result of reported bleeding events in patients taking Celebrex and warfarin concurrently. The "Precautions" section included the following:
- “(a)nticoagulant activity should be monitored, particularly in the first few days, after initiating or changing CELEBREX therapy in patients receiving warfarin or similar agents, since these patients are at an increased risk of bleeding complications ... in post-marketing experience, bleeding events have been reported, predominately in the elderly, in association with increases in prothrombin time in patients receiving CELEBREX concurrently with warfarin.”
- “RE: NDA 20-998, Celebrex (celecoxib) capsules; ‘Warning Letter,’” dated 1 February 2001, Food and Drug Administration, posted 6 February 2001.**
270. Additionally, among the analyst reports I was able to review from the Class Period, not one discussed either the February 2001 warning letter or any of the three previous warning letters. Consequently, I conclude that the warning letter issuance had *de minimis*, if any, valuation impact, and that it caused none of the stock price decline on 6-8 February 2001.

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<sup>62</sup> “Pharmacia Again Warned About Celebrex Promotion,” by Lisa Richwine, *Reuters News*, 6 February 2001.

<sup>63</sup> *Ibid.*



### Conclusion About Confounding Information

271. Carefully considering information that emerged between 6 February and 8 February 2001 indicates that no potentially confounding information significantly contributed to the Pharmacia stock price decline that occurred during that timeframe. I considered whether news over this timeframe about Pfizer and about Merck's COX-2 inhibitor Vioxx was confounding information. I determined that it was not. The decline in the Pharmacia stock price was caused by the corrective disclosure of information about the CLASS study.

## **DAMAGE COMPUTATION**

### **The Inflation Ribbon**

272. An inflation ribbon is a time series indicating how much artificial inflation caused by the alleged fraud was in the stock price on each day of the Class Period.
273. On account of the close mirroring of the information concealed at the start of the Class Period and then disclosed on 6-8 February 2001, the event study results in this case constitute essentially a controlled experiment. The value of Pharmacia Pharmaceutical Stock with the information concealed is observed just prior to 6 February 2001, while the value of the Pharmacia Pharmaceutical Stock with the information disclosed is observed just after the three-day adjustment ending on 8 February 2001. The residual change in the Pharmacia Pharmaceutical Stock Price over this period therefore measures the value of the information at issue.
274. The cumulative residual decline in the Pharmacia Pharmaceutical Stock Price over the three days, 6-8 February 2001, amounted to \$5.92 per share. Prior to 6 February 2001, therefore, the price of Pharmacia's stock was artificially inflated by \$5.92 per share.
275. The inflation ribbon is constructed by working chronologically backwards from the end of the three-day disclosure event window, in this case 8 February 2001, and adding fraud-related residual price declines as they occurred. No artificial inflation remained in the stock price as of 8 February 2001, a day when the residual decline in the Pharmacia Pharmaceutical Stock Price was \$3.39 per share. This means that a day earlier, as of 7 February 2001, the artificial inflation in the Pharmacia stock price was \$3.39 per share.

276. On February 7<sup>th</sup>, the residual stock price decline was \$2.14 per share. Therefore, as of February 6<sup>th</sup>, the artificial inflation amounted to \$5.53 per share, equal to the \$2.14 that dissipated on February 7<sup>th</sup> plus the \$3.39 per share that remained afterwards.
277. On February 6<sup>th</sup>, the residual decline in the Pharmacia Pharmaceutical Stock Price was \$0.39 per share. Therefore, a day earlier, on February 5<sup>th</sup>, the artificial inflation in the Pharmacia stock price amounted to \$5.92 per share, the \$0.39 that dissipated on February 6<sup>th</sup>, plus the \$5.53 per share that remained afterwards.
278. Prior to 6 February 2001, there were no corrective disclosures that observably dissipated artificial inflation during the Class Period. Consequently, the artificial inflation in the Pharmacia stock price was unchanged since the start of the Class Period.
279. The Court of Appeals for the Third Circuit held:

“Plaintiffs’ own expert acknowledges that the announcement of the results of the CLASS study ‘had little measurable effect on [Pharmacia’s] stock price.’ But that fact does not negate a finding of materiality when the market was expecting that the results of the study would be positive, and plaintiffs have presented evidence indicating precisely that. (citing Morgan Stanley report written the day after the CLASS study results were released that states, ‘we are making no change to our forecasts, as we had anticipated the study to corroborate the strong safety profile of the product’). And, of course, the materiality of the alleged misrepresentations is self-evident when we look at the market’s negative reaction – to the tune of a nine-percent drop in stock price in three days – when defendants’ analysis of the CLASS study was questioned in February 2001.”  
*Pharmacia*, 554 F.3d 342, \*352 (internal citations omitted).

280. Exhibit-13 presents the inflation ribbon.

### **Per Share Damage Formula**

281. The measure of damages generally applied in 10b-5 cases is the reduction in the dollar inflation over an investor’s holding period (the economic/inflation loss).
282. For shares sold after the final corrective disclosure, the Private Securities Litigation Reform Act of 1995 (“PSLRA 1995”) limits the damages subject to an investment loss cap based on the price paid for the stock and the market prices prevailing subsequent to the disclosure:

“[T]he award of damages to the plaintiff shall not exceed the difference between the purchase or sale price paid or received, as appropriate, by the plaintiff for the subject security and the mean trading price of that security during the 90-day period beginning on the date on which the information correcting the misstatement or omission that is the basis for the action is disseminated to the market.”

15 U.S.C. § 78u-4(e) (2).

283. To provide a conservative measure of damages, I applied an investment loss cap to shares sold during the Class Period and not just to shares sold afterwards. For any particular holding period, damages are the lesser of the decline in the inflation ribbon and the decline in the share price.

284. According to PSLRA 1995, the investment loss cap for shares sold during the 90-day period following the final corrective disclosure (“the bounce-back period”) are a function of the average of the closing prices from the date of disclosure to the date of sale:

“... if the plaintiff sells or repurchases the subject security prior to the expiration of the 90-day period described in paragraph (1), the plaintiff’s damages shall not exceed the difference between the purchase or sale price paid or received, as appropriate, by the plaintiff for the security and the mean trading price of the security during the period beginning immediately after dissemination of information correcting the misstatement or omission and ending on the date on which the plaintiff sells or repurchases the security.”

15 U.S.C. § 78u-4(e) (2).

285. Thus, damage on any share purchased during the Class Period and sold within 90 days of the final corrective disclosure is the lesser of the reduction in the dollar inflation over the investor’s holding period (the economic/inflation loss) or the decline in the stock price (the investment loss), where the terminal stock price is deemed to be the average price from the final corrective disclosure date to the sale date.

286. Damage on any share purchased during the Class Period and held 90 days or more beyond the final corrective disclosure equals the lesser of the reduction in the dollar inflation over the investor’s holding period (the economic/inflation loss) or the decline in the stock price (the investment loss), where the terminal stock price is deemed to be the average price over the 90 days following the final corrective disclosure.

287. Even though according to the news analysis and event study analysis all artificial inflation dissipated with the 6-8 February 2001 corrective disclosure, the final corrective informational disclosure took place on 5 August 2001 with the publication of the *Washington Post* exposé. The Court of Appeals for the Third Circuit considered this event to be the final disclosure of the fraud and the end of the Class Period.<sup>64</sup> Under this scenario, the 90-day bounce-back period stretches from 5 August 2001 through 2 November 2001. The average price for Pharmacia stock over this 90-day period, based on closing prices, was \$41.25 per share.
288. As an example of how per share damages are computed for a particular investor, consider an investor who purchased Pharmacia stock on 2 January 2001 for \$60.00 per share and sold those shares at the close of trading on 8 February 2001 for \$53.00 per share. The inflation on 2 January 2001 was \$5.92 per share, and at the close on 8 February 2001 it was zero. According to the inflation ribbon, this investor's economic/inflation loss is \$5.92 per share, equal to the decline in inflation over his holding period (\$5.92 - \$0.00). The investment loss is \$7.00 per share, equal to the \$60.00 purchase price minus the \$53.00 per share sale price. The per share damages are the lesser of the economic/inflation loss and the investment loss, which is \$5.92 per share.
289. Based on the foregoing analysis and statutory formulas, Rule 10b-5 damages per share range from \$0 to \$5.92 per share, excluding prejudgment interest. A particular investor's damages depend on when during the Class Period each share was purchased and if and when each respective share was subsequently sold. Investors who purchased after 8 February 2001, or sold their shares prior to 6 February 2001, suffered no damages on those shares.

### **AGGREGATE DAMAGES**

290. Counsel for the Plaintiffs asked me to provide an estimate of the aggregate damages suffered by all investors who bought Pharmacia stock during the Class Period. To estimate aggregate damages, it is necessary to estimate how many Pharmacia shares were bought on each day of the Class Period and to estimate if and when those same shares were

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<sup>64</sup> *Pharmacia*, 554 F.3d 342.

subsequently sold. This information is relevant, because the damage on each particular share depends on when it was bought and when it was sold.

291. The two-trader proportional trading model estimates the requisite purchase and sale dates for all shares traded during the Class Period, and is commonly used to provide estimates of aggregate damages in securities cases.

### **Two-Trader Proportional Trading Model**

292. The two-trader proportional trading model recognizes that most trading volume is attributable to a relatively small subset of traders, while the remaining investors tend to have longer holding periods. Accordingly, market participants are divided into two groups – “traders,” who trade frequently, and “holders,” who trade less frequently.
293. The model employs parameter estimates for the percentages of outstanding shares held by each of the two groups, and the greater frequency of “trader” trades relative to “holder” trades.
294. The model then uses reported trading volume to estimate when share purchases were subsequently sold. Essentially, the model estimates the probability of any particular share being traded on a particular day. Next, it applies this probability to estimate the number of shares purchased on each prior day that are re-traded on each respective subsequent day. The model’s construction and operation are further detailed below.

### **Published Literature, Wide Use, and Acceptance by Courts**

295. A proportional trading model such as the two-trader proportional trading model I used is a “representative agent” model, which is a generally accepted model in finance and economics research. There are a multitude of seminal articles based on representative agent models. The groundbreaking article by Nobel Prize winner Robert E. Lucas, “Asset Prices in an Exchange Economy,” published in the leading journal *Econometrica* [November 1978],<sup>65</sup> is but one such example that demonstrates the profession’s acceptance of such models.

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<sup>65</sup> “Asset Prices in an Exchange Economy” by Robert E. Lucas, Jr., *Econometrica*, November 1978.

296. The basic one-trader and two-trader proportional trading models are presented in the *Litigation Services Handbook*, 3rd edition.<sup>66</sup>
297. In my experience I have observed that the two-trader proportional trading model and its variants are widely used both by plaintiff and defense experts for calculating aggregate damages in the course of litigation, in settlement discussions, and for drafting plans of allocation subsequent to settlement.
298. Published studies, such as Cone and Laurence [1994]<sup>67</sup> and Furbush and Smith [1994]<sup>68</sup>, have examined the model's use in securities litigation and have shown that two-trader models are more conservative and more accurate in estimating damages than are single trader proportional trading models.
299. Finnerty and Pushner [2003]<sup>69</sup> and Barclay and Torchio [2001]<sup>70</sup> are two more examples of published research on the model and its variants.
300. Bassin [2000]<sup>71</sup> and Beaver, Malernee, and Keeley [1993]<sup>72</sup> empirically tested two-trader models. Bassin and Beaver, *et al.*, used actual trading records to calibrate the parameters of two-trader models. I utilized the modeling and parameter estimates presented in the Beaver, *et al.* model, which I have observed to be widely used both by plaintiff and defense experts to estimate aggregate damages.
301. In the following cases, courts have reviewed and accepted proportional trading models for estimating aggregate damages: *In re Oxford Health Plans, Inc.*, 244 F. Supp. 2d 247, 249-52 (S.D.N.Y. 2003); *Robbins v. Deloitte & Touche, LLP*, No. 90-896- -Civ-J-10, 1995 U.S. Dist. LEXIS 22424, at \*1 (M.D. Fla. June 28, 1995), *rev'd on other grounds*, 116 F.3d

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<sup>66</sup> "Securities Act Violations: Estimation of Damages," by Nicholas I. Crew, Patrick G. Goshtigian, Marnie A. Moore, and Atulya Sarin, chapter 17 in *Litigation Services Handbook*, 3<sup>rd</sup> edition, edited by Roman L. Weil, Michael J. Wagner, and Peter B. Frank, John Wiley & Sons Inc., 2001.

<sup>67</sup> "How Accurate Are Estimates of Aggregate Damages in Securities Fraud Cases?," by Kenneth R. Cone and James E. Laurence, *Business Law*, 1994.

<sup>68</sup> "Estimating the Number of Damaged Shares in Securities Fraud Litigation: An Introduction to Stock Trading Models," by Dean Furbush and Jeffrey W. Smith, *Business Law*, 1994.

<sup>69</sup> "An Improved Two-Trader Model for Measuring Damages in Securities Fraud Class Actions," by John Finnerty and George Pushner, *Stanford Journal of Law, Business and Finance*, 2003.

<sup>70</sup> "A Comparison of Trading Models Used for Calculating Aggregate Damages in Securities Litigation", by Michael Barclay and Frank C. Torchio, *Law & Contemporary Problems*, 2001.

<sup>71</sup> "A Two Trader Population Share Retention Model for Estimating Damages in Shareholder Class Action Litigations," by William M. Bassin, *Stanford Journal of Business and Finance*, 2000.

<sup>72</sup> *Stock Trading Behavior and Damage Estimation in Securities Cases*, by William H. Beaver, James K. Malernee, and Michael C. Keeley, Cornerstone Research, 1993.

1441 (11th Cir. 1997); *In re Worldcom, Inc.*, No. 02 civ. 3288 (DLC), 2005 U.S. Dist. LEXIS 3143 at \*5-\*15 (S.D.N.Y. March 4, 2005).

#### Construction of the Two-Trader Model

302. I constructed a 389 row by 328 column matrix whose entries show the estimates of how many shares purchased on each of the 328 trading days in the Class Period were sold on each of the 388 trading days up through 2 November 2001, which is the last trading day of the 90-calendar-day period commencing 5 August 2001.
303. The 389<sup>th</sup> row of the matrix shows how many shares purchased within the Class Period were still held beyond the end of the 90-day period.
304. Based on the parameters in the Beaver, *et al.* study, I assumed that 15.3% of outstanding shares were held by “traders” and the remaining 84.7% were held by “holders.” Also based on their study, I assumed that a trader’s share is 29 times more likely to be traded than is a holder’s share. As noted above, the Beaver, *et al.* study arrived at these estimates by analyzing actual trade data.
305. Pharmacia was traded on the New York Stock Exchange. Since specialists at the NYSE trade in order to maintain an orderly market rather than for investment purposes, trading volume was adjusted to remove the effect of the exchange specialists’ trades. Specialist participation data were provided by the NYSE and is presented in Exhibit-14. The proper adjustment is to remove the specialist participation rate times the daily volume.<sup>73</sup> This adjustment removed 13.2% to 15.9% of daily trading volume, depending on the particular month.
306. Share float for the Company was calculated by adding short interest to total shares outstanding and reducing this amount by insider holdings and by the shares that the institutional holdings data indicated were owned by institutions and not traded during the Class Period. Short interest data are presented in Exhibit-15 and institutional holdings are presented in Exhibit-16. Insider holdings were obtained from Pharmacia’s annual proxy statements filed with the SEC.<sup>74</sup>

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<sup>73</sup> The data provided by the NYSE quote the specialist participation rate as the percentage of volume attributed to specialists rather than the percentage of trades in which specialists participated as buyers or sellers.

<sup>74</sup> According to Proxy Statements filed 22 May 2000 and 16 March 2001, insiders held 4,609,723 and 2,202,778 shares as of 4 May 2000 and 5 March 2001, respectively. For the first 12 days of the Class Period, I used the



307. To make the institutional holdings adjustment to float, I examined each institutions reported holdings on each quarterly reporting date from 31 March 2000 through 31 December 2001. I assumed that, for each institution, the respective minimum level of shares held across those reporting dates was the amount each institution owned prior to the Class Period and continued to hold throughout the Class Period and the subsequent 90 days. I then summed these held shares across institutions to arrive at an aggregate estimate of shares owned by institutions prior to the Class Period and not traded during the Class Period and subsequent 90 days. This is the same methodology described by Barclay and Torchio [2001], among others. The number of shares arrived at through this approach amounted to 407.3 million shares, which I removed from the public float quantity.
308. Reducing the float to account for institutional holdings in this manner is a conservative methodological approach – *i.e.* one that lowers estimated damages – for it reduces the number of shares that could have been damaged and increases the estimate of turnover among the remaining shares. That is, this float reduction attributes reported volume to a smaller number of shares being traded, thereby limiting the number of unique shares that were purchased during the Class Period and hence damaged.
309. This method for excluding shares held by institutions is a conservative approach also because it is possible that some institutions may have sold and then repurchased shares between the quarterly reporting dates. Having been bought at artificially inflated prices, such repurchased shares would have been damaged, and yet my approach excludes them. Furthermore, the removal of held shares from float is conservative in that the trading frequency parameters estimated by Beaver, *et al.*, which I likewise applied, were derived empirically from data that did not remove such float held by institutions.
310. The share float for Pharmacia was divided into shares owned by “traders” and shares owned by “holders” using the Beaver, *et al.* model parameters. For example, on 17 April 2000, total float was 856,581,033 shares. Of this amount 15.3%, equal to 131,056,898 shares, belonged to “traders” and the remaining 84.7%, or 725,524,135 shares, belonged to “holders.” As shares outstanding changed, the number of shares owned by each group was adjusted using these same percentages.

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4,609,723 shares reportedly held as of 4 May 2000 as the approximate number of shares held by insiders after the merger.



311. On each trading day, the probability of any particular trader's share being traded (or re-traded) is estimated as the ratio of traders' volume divided by the number of traders' shares. The probability of any particular holder's share being traded (or re-traded) is estimated as the ratio of holders' volume divided by the number of holders' shares.
312. Using these estimated probabilities for each day in the Class Period, the model indicates when shares that were previously purchased were later sold.
313. Using the two-trader proportional trading model, I constructed a 389 by 328 element matrix whose entries show how many traders' shares purchased on each day were sold on each of the subsequent days. Another 389 by 328 element matrix shows how many holders' shares purchased on each day were sold on each subsequent day. A third matrix, the "buy/sell" matrix, sums the two.
314. To arrive at the estimate of total damages, I multiplied each element of the buy/sell matrix by the Rule 10b-5 per share damage corresponding to the respective buy and sell dates. Total damage to investors in the Plaintiff Class is found by summing the damages for all of the buy/sell dates. Estimated using this model, total damages suffered by Class members amounted to \$1.59 billion. This damage figure is exclusive of prejudgment interest.

#### Analysis of the Two-Trader Model

315. Analysis of the two-trader model with alternative parameters indicates that the model parameters I applied provide one of the most conservative estimates of aggregate damages among estimates derived with alternative parameter value choices.
316. Recall that the parameter values I applied are those presented by Beaver, *et al.* [1993]. Barclay and Torchio [2001] analyzed these parameters and found them to generate nearly the lowest aggregate damage estimates from among the range of potential parameter values.
317. My own analysis of the model as it pertains to the present case confirms the Barclay and Torchio conclusion: the two-trader proportional trading model with the Beaver, *et al.* parameters produces a conservative estimate of aggregate damages. For my analysis, I varied the parameter representing the proportion of shares held by traders versus holders to assess how such variation changed the aggregate damage estimate.
318. Using a 10% value for the proportion of all shares owned by "traders" rather than "holders," for example, aggregate damages are estimated to be \$1.62 billion. This figure is

higher than the \$1.59 billion I estimated using the Beaver, *et al.* parameter value of 15.3%. With a 20% value, aggregate damages are estimated to be \$1.64 billion, also higher than the \$1.59 billion estimated using the 15.3% parameter value. The table below shows estimated aggregate damages for a range of parameter value choices.

Percent Held by Traders	Aggregate Damages (\$ Millions)
0%	3,035.9
3%	2,177.0
5%	1,902.4
10%	1,622.7
15%	1,584.7
15.3%	1,586.1
20%	1,639.4
30%	1,843.4
40%	2,071.8
50%	2,285.9
60%	2,477.1
70%	2,645.2
80%	2,792.5
90%	2,921.8
100%	3,035.9

319. Note that from among the possible values for the model parameter value, the 15.3% input value I used gives an estimate of aggregate damages that is among the lowest. The use of the 15.3% parameter value therefore produces a conservative estimate of aggregate damages. As shown below, other analysis further confirms that the aggregate damages estimate is conservative.

Aggregate Damages Assuming the 90-Day Bounce-Back Period Begins on 8 February 2001

320. As discussed above, I estimated damages for all purchasers of Pharmacia stock through the final corrective disclosure on 5 August 2001 and began the 90-day bounce-back period on that date. The model with this specification estimated aggregate damages to be \$1.59 billion. However, the final corrective disclosure on 5 August 2001 was not the date of the final dissipation of inflation, which occurred on 8 February 2001. Because it may be

determined that the 90-day bounce-back period should commence with the final dissipation of inflation rather than the final corrective disclosure, I performed an alternate estimation of aggregate damages with the 90-day bounce-back period starting on 8 February 2001.

321. The 90-day period beginning 8 February 2001 ends 8 May 2001. The average price for Pharmacia stock over this 90-day period, based on closing prices, was \$50.11 per share.
322. For this alternative aggregate damage estimation, I utilized the same methodology and model parameters as were used in the original calculation.
323. With the 90-day bounce-back period beginning 8 February 2001, total damages suffered by Class members are estimated to be \$1.38 billion, exclusive of prejudgment interest.

#### **Aggregate Damages Estimated from the Institutional Holdings Data**

324. An alternative estimate of aggregate damages can be derived from the holdings data that institutions report quarterly to the SEC.
325. The reporting dates for these data correspond to the end of each calendar quarter. Therefore, to observe institutional holdings during the time spanning the Class Period and subsequent 90 days, I examined institutional holdings data reported for the quarters ending 31 March 2000 through 31 December 2001. These data are presented in Exhibit-16.
326. I observed whether holdings of Pharmacia stock increased or decreased for each respective institution in each quarter. If holdings increased, I assumed the increase equaled the number of shares purchased during the quarter. If holdings decreased, I assumed the decline equaled the number of shares sold during the quarter. If a particular institution's holdings remained the same, I assumed that institution neither bought nor sold shares during the quarter. This is a conservative method for estimating the number of shares traded by institutions, as it equates purchases with net purchases and sales with net sales. In fact, there may have been offsetting purchases and sales within a quarter that would not be captured by the end-of-quarter snapshots.
327. Next, for each institution, I assumed that transactions occurred on a daily basis throughout each respective quarter in proportion to the ratio of each day's market trading volume relative to the total quarterly market trading volume. That is, if on a particular day 5% of the quarter's total trading volume occurred, I assumed that 5% of each institution's trading during the quarter occurred on that day.

328. I then constructed a buy/sell matrix for each institution, similar to the buy/sell matrix described above for the proportional trading model. Initially, I used FIFO (first in, first out) accounting to match sales with buys, but repeated the exercise using LIFO (last in, first out). Under FIFO, the assumption is that when an institution sells shares, those shares sold are the shares that were the first purchased, meaning they would be the oldest shares held at the time of the sale. Under LIFO, the assumption is that the shares an institution sells are those shares that were the most recently purchased. Consequently, for each institution I constructed two alternative buy/sell matrices indicating when shares were purchased and if/when those shares were subsequently sold – one matrix based on FIFO and the other on LIFO.
329. Summing the buy/sell matrices for all institutions produces an aggregate institutional buy/sell matrix that indicates when all institutions as a group bought shares, and if/when those particular shares were later sold.
330. I assigned the appropriate per share damage amount to each purchased share depending on its purchase and sale dates as identified by the aggregate institutional buy/sell matrix. Summing across all purchased shares and all institutions provides a measure of damages suffered by all institutions.
331. Based on this methodology, using FIFO accounting, and assuming the 90-day bounce-back period starts 5 August 2001, I estimated that institutions suffered damages of \$2.25 billion. Using LIFO accounting, institutional damages were \$1.85 billion.
332. Assuming the 90-day bounce-back period begins 8 February 2001, using FIFO accounting, the institutional damage model indicates aggregate institutional damages of \$1.76 billion. Using LIFO accounting, damages amount to \$1.48 billion.
333. Both the FIFO and LIFO institutional damage figures for the later bounce-back period scenario substantially exceed the \$1.59 billion aggregate damage figure estimated by the two-trader proportional trading model, even though this model includes only damages suffered by institutions who must report their holdings to the SEC. Smaller institutions and individual investors are excluded from the holdings data, and are therefore excluded from this damage estimate. Similarly, both the FIFO and LIFO institutional damage figures for the earlier bounce-back period scenario exceed the two-trader proportional trading model's estimate of \$1.38 billion. Based on the greater magnitude of the damage estimates indicated

by the institutional damage model – despite that model’s investor exclusions – I conclude that the estimates provided by the two-trader proportional trading model are extraordinarily conservative.

**LIMITING FACTORS**

334. This report is furnished solely for the purpose of court proceedings in the above named matter and may not be used or referred to for any other purpose. The analysis and opinions contained in this report are based on information available as of the date of this report. I reserve the right to supplement or amend this report, including in the event additional information becomes available.

A handwritten signature in blue ink, reading "Steven P. Feinstein". The signature is fluid and cursive, with the first name "Steven" written in a stylized, abbreviated form.

Steven P. Feinstein, Ph.D., CFA

## **APPENDIX: LOGARITHMIC RETURNS**

Logarithmic returns, rather than percent change returns, are commonly used in stock return regressions and event study analysis. The formula for a logarithmic return is:

$$R_t = \ln \left( \frac{P_t + d_t}{P_{t-1}} \right)$$

where:

$R_t$  is the logarithmic return on day  $t$ ;  
 $P_t$  is the stock price at the end of day  $t$ ;  
 $P_{t-1}$  is the stock price from the previous day, day  $t-1$ ; and  
 $d_t$  is the dividend on day  $t$ , if any.

The formula for converting a logarithmic return into a dollar return is:

$$DR_t = P_{t-1} \cdot (e^{R_t} - 1)$$

where:

$DR_t$  is the dollar return on day  $t$ ;  
 $P_{t-1}$  is the stock price from the previous day, day  $t-1$ ;  
 $e$  is natural  $e$  (approximately 2.7); and  
 $R_t$  is the logarithmic return on day  $t$ .

If a stock falls from \$20 to \$18, the percent change in price is -10%, equal to the \$2 decline divided by the original \$20 price. The logarithmic return, however, is -10.54%, equal to  $\ln(\$18/\$20)$ .

The logarithmic return relates a price change to an average of the original, final, and intervening prices over the course of a price decline. As such, for large price declines, it is possible for a logarithmic price decline to exceed 100%, since the decline may be greater than the average of the beginning and ending prices.

An attractive feature of a logarithmic return is that it can be decomposed into contributing factors linearly. That is, the portion of a logarithmic return caused by company-specific information is isolated by subtracting from the total logarithmic return the portion of the total return caused by market and sector factors.

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**Exhibit-1**

**Documents and Other Information Reviewed and Relied Upon**

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- Deutsche Bank Securities, "Pharmacia," 27 July 2001.
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- UBS, "Pharmacia," 20 September 2001.
- Bear, Stearns & Co., "Pharmacia," 27 September 2001.
- Salomon Smith Barney, "Pharmacia," 5 October 2001.
- Credit Suisse First Boston, "Pharmacia," 15 October 2001.
- Morgan Stanley, "Pharmacia," 15 October 2001.
- UBS, "Pharmacia," 18 October 2001.
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- Salomon Smith Barney, "Pharmacia," 22 October 2001.
- CIBC, "Pharmacia," 23 October 2001.
- Salomon Smith Barney, "Pharmacia," 23 October 2001.
- Deutsche Bank Securities, "Pharmacia," 23 October 2001.
- PNC, "Pharmacia," 23 October 2001.
- Deutsche Bank Securities, "Pharmacia," 24 October 2001.
- Morgan Stanley, "Pharmacia," 24 October 2001.
- Raymond James & Associates, "Pharmacia," 24 October 2001.
- UBS, "Pharmacia," 24 October 2001.
- Ohman Fondkommission, "Pharmacia," 25 October 2001.
- Morgan Stanley, "Pharmacia," 30 October 2001.
- RBC Capital Markets, "Pharmacia," 30 October 2001.
- Salomon Smith Barney, "Pharmacia," 12 November 2001.
- Bear, Stearns & Co., "Pharmacia," 13 November 2001.
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- UBS, "Pharmacia," 15 November 2001.
- Bear, Stearns & Co., "Pharmacia," 19 November 2001.
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**Documents and Other Information Reviewed and Relied Upon**

- CIBC, "Pharmacia," 20 November 2001.
- Morgan Stanley, "Pharmacia," 20 November 2001.
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- Ohman Fondkommission, "Pharmacia," 22 November 2001.
- Bear, Stearns & Co., "Pharmacia," 28 November 2001.
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- Salomon Smith Barney, "Pharmacia," 29 November 2001.
- Credit Suisse First Boston, "Pharmacia," 29 November 2001.
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- Morgan Stanley, "Pharmacia," 29 November 2001.
- Raymond James & Associates, "Pharmacia," 29 November 2001.
- RBS, "Pharmacia," 29 November 2001.
- Sanford C. Bernstein & Co., Inc., "Pharmacia," 29 November 2001.
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- Salomon Smith Barney, "Pharmacia," 3 December 2001.
- Credit Suisse First Boston, "Pharmacia," 3 December 2001.
- Deutsche Bank Securities, "Pharmacia," 6 December 2001.
- UBS, "Pharmacia," 6 December 2001.
- Salomon Smith Barney, "Pharmacia," 7 December 2001.
- UBS, "Pharmacia," 13 December 2001.
- Argus Research, "Pharmacia," 19 December 2001.
- RBS, "Pharmacia," 16 January 2002.
- UBS, "Pharmacia," 17 January 2002.
- Credit Lyonnais Securities (Uk), "Pharmacia," 30 January 2002.
- D. Carnegie A.B., "Pharmacia," 30 January 2002.
- ABG Sundal Collier, "Pharmacia," 4 February 2002.
- Salomon Smith Barney, "Pharmacia," 4 February 2002.
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- Salomon Smith Barney, "Pharmacia," 5 February 2002.
- Credit Suisse First Boston, "Pharmacia," 5 February 2002.
- D. Carnegie A.B., "Pharmacia," 5 February 2002.
- Deutsche Bank Securities, "Pharmacia," 5 February 2002.
- ABG Sundal Collier, "Pharmacia," 6 February 2002.
- Bear, Stearns & Co., "Pharmacia," 6 February 2002.
- Deutsche Bank Securities, "Pharmacia," 6 February 2002.
- Morgan Stanley, "Pharmacia," 6 February 2002.
- Raymond James & Associates, "Pharmacia," 6 February 2002.
- RBS, "Pharmacia," 6 February 2002.

**Exhibit-1**

**Documents and Other Information Reviewed and Relied Upon**

- UBS, "Pharmacia," 6 February 2002.
- D. Carnegie A.B., "Pharmacia," 7 February 2002.
- Credit Suisse First Boston, "Pharmacia," 13 February 2002.
- RBS, "Pharmacia," 19 February 2002.
- Credit Suisse First Boston, "Pharmacia," 20 February 2002.
- Credit Suisse First Boston, "Pharmacia," 15 March 2002.
- Morgan Stanley, "Pharmacia," 18 March 2002.
- Credit Suisse First Boston, "Pharmacia," 20 March 2002.
- Natixis, "Pharmacia," 27 March 2002.
- Salomon Smith Barney, "Pharmacia," 28 March 2002.
- Sanford C. Bernstein & Co., Inc., "Pharmacia," 16 April 2002.
- UBS, "Pharmacia," 18 April 2002.
- ABG Sundal Collier, "Pharmacia," 19 April 2002.
- Bernstein Research, "Pharmacia," 19 April 2002.
- Salomon Smith Barney, "Pharmacia," 22 April 2002.
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- Credit Suisse First Boston, "Pharmacia," 23 April 2002.
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- Raymond James & Associates, "Pharmacia," 24 April 2002.
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- Credit Suisse First Boston, "Pharmacia," 14 May 2002.
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- Credit Suisse First Boston, "Pharmacia," 20 May 2002.
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- LexisNexis
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[<http://www.nyxdata.com/Data-Products/Facts-and-Figures>]
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- Standard & Poor’s
- Vickers Stock Research Corp



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**Documents and Other Information Reviewed and Relied Upon**

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- “Pharmacia/Pfizer Inc Statement on the FDA Arthritis Advisory Committee Meeting,” dated 7 February 2001, Exhibit-314, [DEFS 03101545].
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**OTHER**

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- Any other documents and data cited in the report.

**Exhibit-2**

**Curriculum Vitae  
Steven P. Feinstein, Ph.D., CFA**

Babson College  
Finance Division  
Babson Park, MA 02457  
781-239-5275  
Feinstein@Babson.edu

**EDUCATION**

- 1989 YALE UNIVERSITY  
Ph.D. in Economics (Concentration in Finance)
- 1986 YALE UNIVERSITY  
M.Phil. in Economics
- 1983 YALE UNIVERSITY  
M.A. in Economics
- 1981 POMONA COLLEGE  
B.A. in Economics (Phi Beta Kappa, *cum laude*)

**TEACHING EXPERIENCE**

- 1996 - present BABSON COLLEGE  
Babson Park, MA  
Full-time Faculty, Finance Division  
Associate Professor (2000-present)  
Donald P. Babson Chair in Applied Investments (2002-2010)  
Faculty Director of the Babson College Fund (2002-2009)  
Director of the Stephen D. Cutler Investment Management  
Center (2002-2007)  
Assistant Professor (1996-2000)
- 1990 - 1995 BOSTON UNIVERSITY SCHOOL OF MANAGEMENT  
Boston, MA  
Full-time Faculty, Department of Finance
- 1993 - 1994 WASHINGTON UNIVERSITY, OLIN SCHOOL OF BUSINESS  
St. Louis, MO  
Visiting Assistant Professor, Department of Finance

**Exhibit-2**

**Curriculum Vitae  
Steven P. Feinstein, Ph.D., CFA**

**BUSINESS EXPERIENCE**

2008 - present	CROWNINSHIELD FINANCIAL RESEARCH, INC. Wellesley, MA President and Senior Expert
1996 - 2008	THE MICHEL-SHAKED GROUP Boston, MA Senior Expert (2001 - 2008) Affiliated Expert (1996 - 2001)
1987 - 1990	FEDERAL RESERVE BANK OF ATLANTA Economist

**PROFESSIONAL DESIGNATIONS**

1998 Awarded the Chartered Financial Analyst designation by the Association for Investment Management and Research.

**RESEARCH AWARDS**

1999 Greater Boston Real Estate Board/Real Estate Finance Association – Research Grant and Featured Speaker at Real Estate Finance Association Meetings.

**PAPERS AND PUBLICATIONS**

“Distortion in Corporate Valuation: Implications of Capital Structure Changes” (with Allen Michel and Jacob Oded) *Managerial Finance* (forthcoming).

“Market Signals of Investment Unsuitability” (with Alexander Liss and Steven Achatz) Law360.com, June 3, 2010. Available from <http://www.law360.com/articles/170690>.

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**Curriculum Vitae  
Steven P. Feinstein, Ph.D., CFA**

“Fraud-on-the-market Theory: Is a Market Efficient?” (with Allen Michel and Israel Shaked) *American Bankruptcy Institute Journal*, May 2005.

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**Curriculum Vitae  
Steven P. Feinstein, Ph.D., CFA**

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Book review of *In Who’s Interest: International Banking and American Foreign Policy*, by Benjamin J. Cohen, Yale University Press, in *Federal Reserve Bank Of Atlanta Economic Review*, Summer 1987.

**PRESENTATIONS**

“Determining the Defendant’s Ability to Pay,” at Taxpayers Against Fraud Education Fund Conference, October 2010.

“The Computation of Damages in Securities Fraud Cases,” at the Grant and Eisenhower Institutional Investor Conference, December 2002.

**Exhibit-2**

**Curriculum Vitae  
Steven P. Feinstein, Ph.D., CFA**

“The Role of the Financial Expert in Complex Litigation,” at the Financial Management Association Conference, October 2000.

“Entrepreneurial Incentives and Resource Allocation Among Corporate Venturing Initiatives,” (with Joel Shulman and U. Srinivasa Rangan), Babson Entrepreneurship Research Conference, May 2000.

“Application of Real Options in Purchasing Strategies,” (with Juan Orozco), presented at the International Applied Business Research Conference, March 2000.

“A Future for Real Estate Futures,” (with Linda Stoller) at the Fairfield County chapter of the Real Estate Finance Association, November 1999, and at the Greater Boston Real Estate Board, November 2000.

“Atlanta Park Medical Center v. Hamlin Asset Management,” (with Natalie Taylor) at the 1999 convention of the North American Case Research Association.

“Using Future Worlds™ in the Financial Planning Process,” (with Jeffrey Ellis) at the Institute of Certified Financial Planners Masters Retreat, October 1999.

“Toward a Better Understanding of Real Options: A Weighted Average Discount Rate Approach,” at the 1999 Financial Management Association Conference, the 1999 European Financial Management Association Conference, and the 1999 Multinational Finance Society Conference.

“Just-In-Time Mathematics: Integrating the Teaching of Finance Theory and Mathematics,” (with Gordon Prichett) at the 1999 Financial Management Association Conference.

“Alternative Dow Investments for the Individual Investor: Diamonds, Synthetics, and the Real Thing,” at the 1999 Academy of Financial Services Convention.

“Evidence of Yield Burning in Municipal Refundings” at Financial Management Association Convention, October 1997; Government Finance Officers Association, 1997; and Northeast Regional Convention of the National Association of State Treasurers, 1997.

“Teaching the Strong-Form Efficient Market Hypothesis” at Conference on Classroom Experiments in the Teaching of Economics at University of Virginia, September 1995.

“Efficient Consolidation of Implied Standard Deviations,” (with Shaikh Hamid) at Midwest Finance Association, March 1995.

**Exhibit-2**

**Curriculum Vitae  
Steven P. Feinstein, Ph.D., CFA**

“A Test of Intertemporal Averaging of Implied Volatilities,” (with Shaikh Hamid) at Eastern Finance Association, April 1995.

“Taking Advantage of Volatility: Non-linear Forecasting and Options Strategies,” (with Hassan Ahmed) at Chicago Board of Trade / Chicago Board Options Exchange Conference on Risk Management, February 1992.

“Immunizing Against Interest Rate Risk Using the Macaulay Duration Statistic: An Assessment,” (with Don Smith) at Japan-U.S. Conference on Financial Strategies in the 1990s, Osaka, Japan, August 1991.

“The Hull and White Implied Volatility,” at American Finance Association Convention, December 1990.

**REVIEWED ARTICLES AND BOOKS FOR:**

Harvard Business School Publishing  
Elsevier  
Journal of Economic Education  
Journal of Forensic Economics  
Journal of Risk  
Financial Review  
North American Case Research Association  
Financial Management  
Journal of Business  
Journal of Money, Credit and Banking  
Quarterly Review of Economics and Finance  
Blackwell  
Prentice Hall  
Southwestern Publishing

**COURSES TAUGHT**

Capital Markets  
Mod B: Decision Making and Applications, Finance stream (MBA)  
Financial Reporting and Corporate Finance (MBA)  
Valuation (MBA)  
Investments (MBA and Executive)  
Equity Markets (MBA)  
Fixed Income Analysis (Undergraduate and MBA)  
Babson College Fund (Undergraduate and MBA)  
Options and Futures (Undergraduate)

**Exhibit-2**

**Curriculum Vitae  
Steven P. Feinstein, Ph.D., CFA**

Advanced Derivative Securities (MBA)  
Corporate Finance (MBA and Executive)  
Financial Management (MBA)  
Risk Management (MBA)  
Corporate Financial Strategy (MBA)  
Integrated Management (Undergraduate)  
Cross-Functional Management (Integrated curriculum, Undergraduate)  
Continuous-Time Finance (Doctoral)  
Portfolio Theory / Management Information Systems (Executive)  
Quantitative Methods for Investment Management (Undergraduate and MBA)  
Introduction to Derivatives Securities (Executive)  
International Finance (Executive)

**TEACHING AWARDS**

Reid Teaching Award, Washington University, Olin School of Business, 1993-94.

**SELECT LIST OF MEDIA CITATIONS**

“Bankers Rigging Municipal Contract Bids Admit to Cover-Up Lies,” by William Selway and Martin Z. Braun, *Bloomberg Markets Magazine*, November 24, 2010.

“Hospital Move Presents Buy-Out Groups with New Risks,” by Francesco Guerra, Christopher Bowe, and Rebecca Knight, *Financial Times*, July 15, 2006.

“Funds of Knowledge Add Value,” by Rebecca Knight, *Financial Times*, March 12, 2006.

“City’s Financial Picture Worse Than Ever, Sanders Says,” by Matthew T. Hall, *San Diego Union-Tribune*, January 7, 2006.

“Downer: Stock Market Takes Another Dive,” by John Chesto, *Boston Herald*, July 23, 2002.

“Banks, Developers, Are Main Beneficiaries,” [editorial column] by Steven Feinstein, *The Boston Globe*, March 31, 2002, p. C4.

“Washington Investing: What Michael Saylor is Really Worth,” by Jerry Knight, *The Washington Post*, March 6, 2000.

“IBM Retools Pensions,” by Stephanie Armour, *USA Today*, May 4, 1999.



**Exhibit-2**

**Curriculum Vitae  
Steven P. Feinstein, Ph.D., CFA**

“L.A. MTA’s Law Firm Says Lissack Strategy Will be a Replay,” by Andrea Figler, *Bond Buyer*, September 30, 1998.

“Fed Key Player in Rescue of Floundering Hedge Fund,” by Andrew Fraser, Associated Press, September 25, 1998.

“Top Banks Plan Bailout for Fund,” by Andrew Fraser, Associated Press, September 24, 1998.

“Clarion Call to the Small Investor,” by Jo-Ann Johnston, *The Boston Globe*, March 4, 1998.

“L.A. Authority Study Shows Rampant Yield Burning Abuse,” by Michael Stanton, *The Bond Buyer*, April 22, 1997.

“Dispute Over Yield Burning Dominates GFOA Session,” by Michael Stanton, *The Bond Buyer*, January 29, 1997.

“Men Behaving Badly (Yield Burning),” *Grants Municipal Bond Observer*, January 24, 1997.

“Municipal Bond Dealers Face Scrutiny,” by Peter Truell, *The New York Times*, December 17, 1996.

“Iowa Market Takes Stock of Presidential Candidates,” by Stanley W. Angrist, *The Wall Street Journal*, August 28, 1995.

“Looking for Clues in Options Prices,” by Sylvia Nasar, *The New York Times*, July 18, 1991.

“For Fed, A New Set of Tea Leaves,” by Sylvia Nasar, *The New York Times*, July 5, 1991.

**MEMBERSHIP IN PROFESSIONAL SOCIETIES**

American Finance Association  
Boston Security Analysts Society  
Chartered Financial Analyst Institute  
Financial Management Association  
Foundation for Advancement of Research in Financial Economics (founding member)  
North American Case Research Association

**Exhibit-3**

**Steven P. Feinstein, Ph.D., CFA  
Testimony in the Last 4 Years**

In Re Veeco Instruments, Inc. Securities Litigation  
United States District Court  
Southern District of New York  
Case No.: 7:05-md-1695 (CM)  
Deposition Testimony  
June 2007

Ellington Overseas Partners. LTD. and Ellington Long Term Fund. LTD. vs.  
HSBC Securities (USA) Inc.  
United States District Court  
Southern District of New York  
06-CV-02353  
July 2007

Carpenters Health & Welfare Fund, *et al.* vs. The Coca-Cola Company  
United States District Court  
Northern District of Georgia  
Atlanta Division  
File No. 1:00-CV-2838-WBH  
Deposition Testimony  
August 2007

In Re Schering-Plough Corporation Securities Litigation  
United States District Court  
For The District of New Jersey  
Master File No. 01-CV-0829 (KSH/MF)  
Deposition Testimony  
September 2007

In Re ProQuest Company Securities Litigation  
United States District Court  
Eastern District Of Michigan  
Master File No. 2:06-cv-10619  
Deposition Testimony  
May 2008

Marvin Overby, *et al.* vs. Tyco International, Ltd., *et al.*  
United States District Court  
District of New Hampshire  
Case No. 02-CV-1357-B  
Deposition Testimony  
May 2008

**Exhibit-3**

**Steven P. Feinstein, Ph.D., CFA  
Testimony in the Last 4 Years**

Franz Schleicher, *et al.* vs. Gary C. Wendt, *et al.*  
(Conseco, Inc.)  
United States District Court  
Southern District of Indiana  
Indianapolis Division  
No. 02 CV 1332 DFH-TAB  
Deposition Testimony  
July 2008

In Re The Mills Corporation Securities Litigation  
United States District Court  
For The Eastern District of Virginia  
Alexandria Division  
Civil Action No. 1:06-cv-00077 (LO/TJR)  
Deposition Testimony  
September 2008

In Re Cooper Companies, Inc. Securities Litigation  
United States District Court  
Central District of California, Southern Division  
No. SACV-06-00169-CJC(RNBx)  
Deposition Testimony  
October 2008 and December 2009

Debra Hall, *et al.* vs. The Children's Place Retail Stores, Inc., *et al.*  
United States District Court  
Southern District of New York  
Civil Action No. 1:07-cv-08252-SAS  
Deposition Testimony  
December 2008

Robert Ross, *et al.* vs. Abercrombie & Fitch Company, *et al.*  
United States District Court  
Southern District of Ohio  
Eastern Division  
No. 2:05-cv-00819-EAS-TPK  
Deposition Testimony  
February 2009

**Exhibit-3**

**Steven P. Feinstein, Ph.D., CFA  
Testimony in the Last 4 Years**

In Re Comcast Corporation ERISA Litigation  
United States District Court  
Eastern District of Pennsylvania  
Master File No. 2:08-cv-00773-HB  
Deposition Testimony  
July 2009

John Richard Beach, *et al.* vs. Healthways Inc., *et al.*  
United States District Court  
Middle District of Tennessee  
Nashville Division  
Civil Action No. 3:08-cv-00569  
Deposition Testimony  
July 2009

Jan Buettgen, *et al.* vs. Katherine J. Harless, *et al.*  
United States District Court  
Northern District of Texas  
Dallas Division  
Civil Action No. 3:09-cv-00791-K  
Deposition Testimony  
December 2010

Vasili Tsereteli, *et ano.*, vs. Residential Asset Securitization Trust 2006-A8, *et al.*  
Civil Action No. 1:08-cv-10637-LAK  
In Re IndyMac Mortgage-Backed Securities Litigation  
Civil Action No. 1:09-cv-04583-LAK  
United States District Court  
Southern District of New York  
Deposition Testimony  
January 2011

In Re Merck & Co., Inc. Securities, Derivative & “ERISA” Litigation  
United States District Court  
District of New Jersey  
Civil Action No. 05-2369(SRC)  
Deposition Testimony  
May 2011

**Exhibit-3**

**Steven P. Feinstein, Ph.D., CFA  
Testimony in the Last 4 Years**

The Board of Trustees of the Southern California IBEW-NECA Defined Contribution Plan, vs.  
The Bank of New York Mellon Corporation and BNY Mellon, National Association.  
United States District Court  
Southern District of New York  
Civil Action No. 1:09-cv-06273-RMB-AJP  
Deposition Testimony  
March 2011 and May 2011

## Exhibit-4

### Pharmacia Corp. (PHA) Stock Prices, Dividends, Volume, and Returns

14 April 2000 through 2 November 2001

Date	PHA Closing Price	PHA Dividend	PHA Logarithmic Return	PHA Volume
4/14/2000	\$53.13	-		4,713,599
4/17/2000	\$54.13	-	1.86%	5,782,199
4/18/2000	\$53.06	-	-1.98%	4,932,099
4/19/2000	\$59.75	-	11.87%	9,619,099
4/20/2000	\$58.25	-	-2.54%	7,218,000
4/24/2000	\$58.06	-	-0.32%	5,731,599
4/25/2000	\$54.00	-	-7.25%	7,264,899
4/26/2000	\$52.75	-	-2.34%	8,837,599
4/27/2000	\$52.50	-	-0.48%	3,947,599
4/28/2000	\$49.94	-	-5.00%	7,654,101
5/1/2000	\$49.63	-	-0.63%	7,083,799
5/2/2000	\$50.00	-	0.75%	5,329,099
5/3/2000	\$51.00	-	1.98%	4,598,199
5/4/2000	\$52.25	-	2.42%	5,897,799
5/5/2000	\$54.00	-	3.29%	4,814,399
5/8/2000	\$55.56	-	2.85%	4,452,500
5/9/2000	\$55.56	-	0.00%	5,655,399
5/10/2000	\$54.13	-	-2.62%	5,801,199
5/11/2000	\$54.38	-	0.46%	3,496,399
5/12/2000	\$53.50	-	-1.62%	2,908,299
5/15/2000	\$55.19	-	3.11%	3,332,899
5/16/2000	\$53.75	-	-2.64%	2,754,099
5/17/2000	\$52.94	-	-1.52%	3,043,000
5/18/2000	\$52.50	-	-0.83%	3,359,399
5/19/2000	\$54.94	-	4.54%	3,669,000
5/22/2000	\$53.19	-	-3.24%	3,192,199
5/23/2000	\$53.50	-	0.59%	4,210,000
5/24/2000	\$51.81	-	-3.21%	4,142,500
5/25/2000	\$52.13	-	0.60%	3,535,699
5/26/2000	\$51.75	-	-0.72%	2,479,699
5/30/2000	\$50.50	-	-2.45%	2,267,000
5/31/2000	\$51.94	-	2.81%	2,329,199
6/1/2000	\$51.81	-	-0.24%	3,032,099
6/2/2000	\$49.31	-	-4.95%	4,790,899
6/5/2000	\$50.00	-	1.38%	3,188,299
6/6/2000	\$48.94	-	-2.15%	3,843,299

## Exhibit-4

### Pharmacia Corp. (PHA) Stock Prices, Dividends, Volume, and Returns

14 April 2000 through 2 November 2001

Date	PHA Closing Price	PHA Dividend	PHA Logarithmic Return	PHA Volume
6/7/2000	\$50.50	-	3.14%	3,185,899
6/8/2000	\$50.13	-	-0.75%	1,660,699
6/9/2000	\$52.06	-	3.79%	2,561,699
6/12/2000	\$52.13	-	0.12%	2,616,799
6/13/2000	\$53.13	-	1.90%	3,531,199
6/14/2000	\$54.75	-	3.01%	3,313,399
6/15/2000	\$55.75	-	1.81%	3,407,799
6/16/2000	\$56.06	-	0.56%	4,275,699
6/19/2000	\$56.50	-	0.78%	3,241,699
6/20/2000	\$56.56	-	0.11%	3,541,599
6/21/2000	\$55.44	-	-2.01%	3,573,199
6/22/2000	\$51.75	-	-6.88%	5,667,199
6/23/2000	\$53.06	-	2.50%	3,784,299
6/26/2000	\$53.38	-	0.59%	3,396,599
6/27/2000	\$53.56	-	0.35%	3,731,899
6/28/2000	\$51.81	-	-3.32%	3,028,099
6/29/2000	\$50.50	-	-2.57%	7,798,500
6/30/2000	\$51.69	\$0.12	2.56%	8,765,898
7/3/2000	\$52.88	-	2.27%	1,583,699
7/5/2000	\$53.50	-	1.18%	3,074,899
7/6/2000	\$54.13	-	1.16%	2,130,399
7/7/2000	\$54.81	-	1.26%	5,106,599
7/10/2000	\$56.06	-	2.25%	4,132,099
7/11/2000	\$57.31	-	2.21%	4,020,899
7/12/2000	\$56.69	-	-1.10%	3,299,799
7/13/2000	\$55.56	-	-2.00%	4,241,599
7/14/2000	\$55.75	-	0.34%	3,934,199
7/17/2000	\$55.75	-	0.00%	2,026,799
7/18/2000	\$55.00	-	-1.35%	2,037,199
7/19/2000	\$53.50	-	-2.77%	3,989,299
7/20/2000	\$52.56	-	-1.77%	4,741,699
7/21/2000	\$52.00	-	-1.08%	4,450,000
7/24/2000	\$52.50	-	0.96%	4,751,099
7/25/2000	\$55.63	-	5.78%	11,599,000
7/26/2000	\$55.88	-	0.45%	5,709,699
7/27/2000	\$55.88	-	0.00%	5,811,299

## Exhibit-4

### Pharmacia Corp. (PHA) Stock Prices, Dividends, Volume, and Returns

14 April 2000 through 2 November 2001

Date	PHA Closing Price	PHA Dividend	PHA Logarithmic Return	PHA Volume
7/28/2000	\$55.81	-	-0.11%	5,220,699
7/31/2000	\$54.75	-	-1.92%	3,084,000
8/1/2000	\$55.75	-	1.81%	4,171,599
8/2/2000	\$57.56	-	3.20%	4,055,799
8/3/2000	\$57.00	-	-0.98%	7,304,099
8/4/2000	\$56.88	-	-0.22%	4,803,599
8/7/2000	\$57.63	-	1.31%	5,488,500
8/8/2000	\$58.81	-	2.04%	7,390,500
8/9/2000	\$57.56	-	-2.15%	5,188,899
8/10/2000	\$55.75	-	-3.20%	4,389,500
8/11/2000	\$56.19	-	0.78%	2,875,899
8/14/2000	\$56.13	-	-0.11%	1,571,299
8/15/2000	\$56.81	-	1.22%	2,588,199
8/16/2000	\$57.75	-	1.64%	3,075,299
8/17/2000	\$59.69	-	3.30%	4,408,299
8/18/2000	\$58.00	-	-2.87%	3,603,000
8/21/2000	\$57.88	-	-0.22%	2,489,899
8/22/2000	\$57.31	-	-0.98%	2,175,399
8/23/2000	\$57.50	-	0.33%	2,690,899
8/24/2000	\$58.56	-	1.83%	2,845,099
8/25/2000	\$59.00	-	0.74%	2,174,799
8/28/2000	\$58.13	-	-1.49%	2,199,799
8/29/2000	\$58.88	-	1.28%	3,132,599
8/30/2000	\$58.56	-	-0.53%	2,806,299
8/31/2000	\$58.56	-	0.00%	3,195,199
9/1/2000	\$58.38	-	-0.32%	2,648,899
9/5/2000	\$56.44	-	-3.38%	4,011,000
9/6/2000	\$55.94	-	-0.89%	3,528,599
9/7/2000	\$56.69	-	1.33%	3,376,399
9/8/2000	\$54.81	-	-3.36%	2,849,599
9/11/2000	\$54.44	-	-0.69%	2,878,399
9/12/2000	\$54.50	-	0.11%	3,009,699
9/13/2000	\$55.25	-	1.37%	4,533,199
9/14/2000	\$54.75	-	-0.91%	3,041,699
9/15/2000	\$54.00	-	-1.38%	6,498,500
9/18/2000	\$53.00	-	-1.87%	2,753,899



## Exhibit-4

### Pharmacia Corp. (PHA) Stock Prices, Dividends, Volume, and Returns

14 April 2000 through 2 November 2001

Date	PHA Closing Price	PHA Dividend	PHA Logarithmic Return	PHA Volume
9/19/2000	\$53.94	-	1.75%	2,146,699
9/20/2000	\$54.31	-	0.69%	2,812,000
9/21/2000	\$56.00	-	3.06%	6,654,000
9/22/2000	\$58.94	-	5.11%	8,865,599
9/25/2000	\$58.94	-	0.00%	5,727,399
9/26/2000	\$58.00	-	-1.60%	5,462,799
9/27/2000	\$58.44	-	0.75%	5,316,099
9/28/2000	\$60.06	-	2.74%	9,734,399
9/29/2000	\$60.19	-	0.21%	5,099,000
10/2/2000	\$57.56	-	-4.46%	4,511,699
10/3/2000	\$57.69	\$0.12	0.42%	3,499,599
10/4/2000	\$57.06	-	-1.09%	3,007,000
10/5/2000	\$57.50	-	0.76%	4,217,199
10/6/2000	\$56.88	-	-1.09%	4,069,000
10/9/2000	\$56.31	-	-0.99%	2,791,500
10/10/2000	\$58.00	-	2.95%	7,317,899
10/11/2000	\$57.81	-	-0.32%	5,049,899
10/12/2000	\$57.50	-	-0.54%	7,451,599
10/13/2000	\$54.94	-	-4.56%	8,388,000
10/16/2000	\$55.19	-	0.45%	4,728,599
10/17/2000	\$56.44	-	2.24%	4,890,899
10/18/2000	\$55.00	-	-2.58%	4,933,599
10/19/2000	\$53.56	-	-2.65%	5,454,799
10/20/2000	\$50.75	-	-5.39%	8,127,500
10/23/2000	\$53.88	-	5.98%	6,452,599
10/24/2000	\$55.00	-	2.07%	4,979,799
10/25/2000	\$56.88	-	3.35%	5,221,599
10/26/2000	\$55.81	-	-1.89%	6,032,000
10/27/2000	\$54.63	-	-2.15%	4,177,099
10/30/2000	\$52.63	-	-3.73%	11,539,000
10/31/2000	\$55.00	-	4.41%	8,070,199
11/1/2000	\$57.44	-	4.34%	5,603,099
11/2/2000	\$58.00	-	0.97%	5,588,000
11/3/2000	\$56.25	-	-3.06%	4,446,500
11/6/2000	\$57.56	-	2.31%	3,430,799
11/7/2000	\$57.50	-	-0.11%	3,826,399

## Exhibit-4

### Pharmacia Corp. (PHA) Stock Prices, Dividends, Volume, and Returns

14 April 2000 through 2 November 2001

Date	PHA Closing Price	PHA Dividend	PHA Logarithmic Return	PHA Volume
11/8/2000	\$59.44	-	3.31%	6,637,299
11/9/2000	\$59.25	-	-0.32%	4,484,799
11/10/2000	\$59.25	-	0.00%	3,749,399
11/13/2000	\$57.25	-	-3.43%	3,507,899
11/14/2000	\$58.75	-	2.59%	3,606,799
11/15/2000	\$58.25	-	-0.85%	2,386,799
11/16/2000	\$57.00	-	-2.17%	2,853,199
11/17/2000	\$59.81	-	4.82%	7,119,599
11/20/2000	\$59.50	-	-0.52%	2,864,699
11/21/2000	\$59.63	-	0.21%	2,743,599
11/22/2000	\$58.06	-	-2.66%	3,336,000
11/24/2000	\$57.69	-	-0.65%	889,900
11/27/2000	\$59.50	-	3.09%	3,540,699
11/28/2000	\$59.25	-	-0.42%	3,945,000
11/29/2000	\$60.94	-	2.81%	5,749,800
11/30/2000	\$61.00	-	0.10%	9,965,398
12/1/2000	\$57.50	-	-5.91%	7,264,700
12/4/2000	\$59.06	-	2.68%	4,419,100
12/5/2000	\$59.75	-	1.16%	3,993,000
12/6/2000	\$57.75	-	-3.40%	5,372,600
12/7/2000	\$58.00	-	0.43%	2,373,200
12/8/2000	\$59.00	-	1.71%	3,680,600
12/11/2000	\$58.69	-	-0.53%	2,979,100
12/12/2000	\$57.81	-	-1.50%	4,880,500
12/13/2000	\$58.56	-	1.29%	5,442,000
12/14/2000	\$59.31	-	1.27%	6,172,700
12/15/2000	\$59.63	-	0.53%	6,385,500
12/18/2000	\$59.38	-	-0.42%	2,876,400
12/19/2000	\$58.00	-	-2.34%	3,827,800
12/20/2000	\$59.94	-	3.29%	2,814,700
12/21/2000	\$58.06	-	-3.18%	6,079,400
12/22/2000	\$57.44	-	-1.08%	3,402,100
12/26/2000	\$58.63	-	2.05%	2,102,900
12/27/2000	\$60.00	-	2.32%	6,231,100
12/28/2000	\$60.94	-	1.55%	2,514,100
12/29/2000	\$61.00	-	0.10%	2,363,600

## Exhibit-4

### Pharmacia Corp. (PHA) Stock Prices, Dividends, Volume, and Returns

14 April 2000 through 2 November 2001

Date	PHA Closing Price	PHA Dividend	PHA Logarithmic Return	PHA Volume
1/2/2001	\$60.00	-	-1.65%	4,105,100
1/3/2001	\$57.00	-	-5.13%	6,933,200
1/4/2001	\$55.31	\$0.12	-2.79%	11,038,100
1/5/2001	\$56.38	-	1.90%	5,976,800
1/8/2001	\$56.50	-	0.22%	4,151,600
1/9/2001	\$55.69	-	-1.45%	4,075,500
1/10/2001	\$55.50	-	-0.34%	4,415,200
1/11/2001	\$54.94	-	-1.02%	5,852,800
1/12/2001	\$55.50	-	1.02%	4,405,200
1/16/2001	\$56.31	-	1.45%	3,630,100
1/17/2001	\$55.88	-	-0.78%	3,061,100
1/18/2001	\$56.81	-	1.66%	3,596,500
1/19/2001	\$56.25	-	-1.00%	4,558,500
1/22/2001	\$56.19	-	-0.11%	3,709,800
1/23/2001	\$55.56	-	-1.12%	4,311,200
1/24/2001	\$55.38	-	-0.34%	4,685,400
1/25/2001	\$55.50	-	0.23%	6,199,700
1/26/2001	\$55.81	-	0.56%	3,374,100
1/29/2001	\$55.40	-	-0.74%	3,325,000
1/30/2001	\$55.18	-	-0.40%	3,597,100
1/31/2001	\$56.02	-	1.51%	3,670,100
2/1/2001	\$57.08	-	1.87%	3,962,200
2/2/2001	\$57.81	-	1.27%	3,231,600
2/5/2001	\$58.28	-	0.81%	3,308,400
2/6/2001	\$57.65	-	-1.09%	4,159,500
2/7/2001	\$56.13	-	-2.67%	5,008,600
2/8/2001	\$53.00	-	-5.74%	12,338,600
2/9/2001	\$54.00	-	1.87%	8,808,500
2/12/2001	\$54.23	-	0.43%	4,268,000
2/13/2001	\$51.63	-	-4.91%	10,655,100
2/14/2001	\$51.90	-	0.52%	7,716,600
2/15/2001	\$52.02	-	0.23%	5,844,100
2/16/2001	\$51.16	-	-1.67%	3,813,800
2/20/2001	\$49.95	-	-2.39%	5,150,600
2/21/2001	\$48.85	-	-2.23%	9,971,500
2/22/2001	\$49.25	-	0.82%	5,719,300

## Exhibit-4

### Pharmacia Corp. (PHA) Stock Prices, Dividends, Volume, and Returns

14 April 2000 through 2 November 2001

Date	PHA Closing Price	PHA Dividend	PHA Logarithmic Return	PHA Volume
2/23/2001	\$49.05	-	-0.41%	5,176,600
2/26/2001	\$49.40	-	0.71%	5,414,500
2/27/2001	\$50.25	-	1.71%	7,799,800
2/28/2001	\$51.70	-	2.84%	5,935,900
3/1/2001	\$51.97	-	0.52%	6,849,300
3/2/2001	\$52.79	-	1.57%	3,626,700
3/5/2001	\$54.05	-	2.36%	4,273,500
3/6/2001	\$52.85	-	-2.25%	5,783,400
3/7/2001	\$51.01	-	-3.54%	3,820,300
3/8/2001	\$50.74	-	-0.53%	4,733,300
3/9/2001	\$51.19	-	0.88%	2,698,700
3/12/2001	\$50.22	-	-1.91%	3,619,900
3/13/2001	\$49.10	-	-2.26%	5,754,000
3/14/2001	\$47.80	-	-2.68%	5,247,500
3/15/2001	\$47.46	-	-0.71%	4,981,100
3/16/2001	\$45.18	-	-4.92%	7,619,200
3/19/2001	\$47.16	-	4.29%	5,121,400
3/20/2001	\$47.12	-	-0.08%	4,104,900
3/21/2001	\$46.58	-	-1.15%	4,898,200
3/22/2001	\$44.00	-	-5.70%	9,557,500
3/23/2001	\$46.99	-	6.57%	8,103,300
3/26/2001	\$48.28	-	2.71%	5,072,200
3/27/2001	\$49.60	-	2.70%	5,115,800
3/28/2001	\$49.80	-	0.40%	3,598,000
3/29/2001	\$49.87	-	0.14%	4,030,700
3/30/2001	\$50.37	-	1.00%	3,566,700
4/2/2001	\$49.25	-	-2.25%	3,026,000
4/3/2001	\$48.76	-	-1.00%	2,918,000
4/4/2001	\$49.23	-	0.96%	3,589,500
4/5/2001	\$51.04	-	3.61%	3,244,000
4/6/2001	\$50.65	\$0.12	-0.53%	3,769,000
4/9/2001	\$52.25	-	3.11%	3,376,300
4/10/2001	\$51.20	-	-2.03%	3,937,400
4/11/2001	\$50.11	-	-2.15%	4,380,200
4/12/2001	\$50.70	-	1.17%	3,141,400
4/16/2001	\$50.45	-	-0.49%	2,848,300

## Exhibit-4

### Pharmacia Corp. (PHA) Stock Prices, Dividends, Volume, and Returns

14 April 2000 through 2 November 2001

Date	PHA Closing Price	PHA Dividend	PHA Logarithmic Return	PHA Volume
4/17/2001	\$52.08	-	3.18%	3,791,700
4/18/2001	\$50.75	-	-2.59%	5,343,200
4/19/2001	\$49.70	-	-2.09%	7,118,000
4/20/2001	\$48.55	-	-2.34%	7,475,300
4/23/2001	\$48.50	-	-0.10%	3,386,700
4/24/2001	\$48.01	-	-1.02%	3,410,400
4/25/2001	\$49.10	-	2.24%	4,814,600
4/26/2001	\$51.51	-	4.79%	4,426,700
4/27/2001	\$52.25	-	1.43%	2,984,600
4/30/2001	\$52.26	-	0.02%	3,965,500
5/1/2001	\$51.72	-	-1.04%	4,293,200
5/2/2001	\$51.00	-	-1.40%	3,609,900
5/3/2001	\$50.00	-	-1.98%	3,218,800
5/4/2001	\$50.00	-	0.00%	5,909,100
5/7/2001	\$48.95	-	-2.12%	4,486,100
5/8/2001	\$48.20	-	-1.54%	4,003,700
5/9/2001	\$47.49	-	-1.48%	7,355,300
5/10/2001	\$46.98	-	-1.08%	6,307,000
5/11/2001	\$46.15	-	-1.78%	5,216,500
5/14/2001	\$46.28	-	0.28%	5,616,800
5/15/2001	\$45.99	-	-0.63%	6,999,900
5/16/2001	\$48.38	-	5.07%	5,860,000
5/17/2001	\$49.49	-	2.27%	6,453,000
5/18/2001	\$49.60	-	0.22%	4,609,500
5/21/2001	\$50.02	-	0.84%	4,937,700
5/22/2001	\$49.50	-	-1.05%	4,866,700
5/23/2001	\$48.74	-	-1.55%	5,012,900
5/24/2001	\$48.69	-	-0.10%	4,140,700
5/25/2001	\$48.56	-	-0.27%	2,923,100
5/29/2001	\$48.01	-	-1.14%	5,039,200
5/30/2001	\$48.25	-	0.50%	3,489,900
5/31/2001	\$48.56	-	0.64%	3,689,800
6/1/2001	\$49.35	-	1.61%	3,187,800
6/4/2001	\$49.66	-	0.63%	1,390,700
6/5/2001	\$49.60	-	-0.12%	2,973,600
6/6/2001	\$49.35	-	-0.51%	2,981,800

## Exhibit-4

### Pharmacia Corp. (PHA) Stock Prices, Dividends, Volume, and Returns

14 April 2000 through 2 November 2001

Date	PHA Closing Price	PHA Dividend	PHA Logarithmic Return	PHA Volume
6/7/2001	\$49.81	-	0.93%	2,215,200
6/8/2001	\$49.70	-	-0.22%	1,902,900
6/11/2001	\$49.06	-	-1.30%	3,249,600
6/12/2001	\$48.97	-	-0.18%	2,681,100
6/13/2001	\$48.75	-	-0.45%	2,321,000
6/14/2001	\$48.15	-	-1.24%	2,933,200
6/15/2001	\$48.80	-	1.34%	5,873,000
6/18/2001	\$49.19	-	0.80%	2,145,100
6/19/2001	\$49.51	-	0.65%	2,424,300
6/20/2001	\$50.75	-	2.47%	5,422,200
6/21/2001	\$51.50	-	1.47%	5,958,600
6/22/2001	\$48.79	-	-5.41%	8,505,200
6/25/2001	\$48.85	-	0.12%	5,650,700
6/26/2001	\$48.43	-	-0.86%	4,608,100
6/27/2001	\$47.22	-	-2.53%	4,714,000
6/28/2001	\$47.12	-	-0.21%	6,102,500
6/29/2001	\$45.95	-	-2.51%	6,675,900
7/2/2001	\$46.58	-	1.36%	4,884,500
7/3/2001	\$46.59	-	0.02%	1,798,700
7/5/2001	\$46.50	-	-0.19%	2,140,900
7/6/2001	\$46.00	-	-1.08%	2,736,800
7/9/2001	\$46.81	\$0.14	2.03%	3,451,300
7/10/2001	\$46.95	-	0.30%	3,696,500
7/11/2001	\$46.70	-	-0.53%	4,581,600
7/12/2001	\$46.22	-	-1.03%	3,947,400
7/13/2001	\$46.85	-	1.35%	3,385,400
7/16/2001	\$42.84	-	-8.95%	13,389,600
7/17/2001	\$42.60	-	-0.56%	8,441,000
7/18/2001	\$43.15	-	1.28%	8,254,300
7/19/2001	\$43.35	-	0.46%	6,450,200
7/20/2001	\$43.65	-	0.69%	3,305,400
7/23/2001	\$43.41	-	-0.55%	3,079,400
7/24/2001	\$42.00	-	-3.30%	5,424,100
7/25/2001	\$42.12	-	0.29%	5,279,100
7/26/2001	\$41.85	-	-0.64%	7,593,600
7/27/2001	\$42.12	-	0.64%	6,397,300

## Exhibit-4

### Pharmacia Corp. (PHA) Stock Prices, Dividends, Volume, and Returns

14 April 2000 through 2 November 2001

Date	PHA Closing Price	PHA Dividend	PHA Logarithmic Return	PHA Volume
7/30/2001	\$43.28	-	2.72%	5,863,100
7/31/2001	\$44.62	-	3.05%	7,969,900
8/1/2001	\$44.55	-	-0.16%	4,041,000
8/2/2001	\$43.90	-	-1.47%	4,655,500
8/3/2001	\$44.00	-	0.23%	4,137,400
8/6/2001	\$44.00	-	0.00%	3,648,100
8/7/2001	\$45.10	-	2.47%	5,126,200
8/8/2001	\$44.32	-	-1.74%	3,071,800
8/9/2001	\$44.35	-	0.07%	3,727,600
8/10/2001	\$44.68	-	0.74%	2,782,500
8/13/2001	\$45.35	-	1.49%	2,690,600
8/14/2001	\$44.90	-	-1.00%	2,344,100
8/15/2001	\$44.87	-	-0.07%	2,625,700
8/16/2001	\$45.00	-	0.29%	2,813,600
8/17/2001	\$44.44	-	-1.25%	1,600,000
8/20/2001	\$44.25	-	-0.43%	2,631,400
8/21/2001	\$44.16	-	-0.20%	3,786,500
8/22/2001	\$43.20	-	-2.20%	7,656,400
8/23/2001	\$42.40	-	-1.87%	7,543,800
8/24/2001	\$41.81	-	-1.40%	8,482,100
8/27/2001	\$41.83	-	0.05%	4,196,700
8/28/2001	\$41.30	-	-1.28%	3,438,500
8/29/2001	\$40.51	-	-1.93%	3,176,200
8/30/2001	\$39.90	-	-1.52%	5,528,200
8/31/2001	\$39.60	-	-0.75%	4,955,000
9/4/2001	\$40.00	-	1.01%	5,743,900
9/5/2001	\$40.80	-	1.98%	5,735,600
9/6/2001	\$40.81	-	0.02%	6,356,600
9/7/2001	\$40.27	-	-1.33%	6,231,300
9/10/2001	\$40.15	-	-0.30%	6,080,100
9/17/2001	\$39.50	-	-1.63%	10,071,800
9/18/2001	\$39.60	-	0.25%	6,603,000
9/19/2001	\$40.00	-	1.01%	10,466,500
9/20/2001	\$38.91	-	-2.76%	7,281,500
9/21/2001	\$38.35	-	-1.45%	7,366,400
9/24/2001	\$37.60	-	-1.98%	5,716,800

## Exhibit-4

### Pharmacia Corp. (PHA) Stock Prices, Dividends, Volume, and Returns

14 April 2000 through 2 November 2001

Date	PHA Closing Price	PHA Dividend	PHA Logarithmic Return	PHA Volume
9/25/2001	\$37.86	-	0.69%	8,235,400
9/26/2001	\$38.74	-	2.30%	5,562,600
9/27/2001	\$40.06	-	3.35%	5,128,700
9/28/2001	\$40.56	-	1.24%	5,020,200
10/1/2001	\$40.75	-	0.47%	3,580,300
10/2/2001	\$41.31	-	1.36%	3,445,800
10/3/2001	\$40.98	-	-0.80%	4,166,000
10/4/2001	\$40.05	-	-2.30%	3,524,100
10/5/2001	\$40.38	-	0.82%	3,847,600
10/8/2001	\$39.94	-	-1.10%	2,758,500
10/9/2001	\$40.00	\$0.14	0.49%	3,808,900
10/10/2001	\$40.41	-	1.02%	3,605,600
10/11/2001	\$41.02	-	1.50%	6,738,100
10/12/2001	\$41.03	-	0.02%	3,214,900
10/15/2001	\$41.00	-	-0.07%	4,211,000
10/16/2001	\$41.20	-	0.49%	4,598,100
10/17/2001	\$41.80	-	1.45%	6,338,400
10/18/2001	\$41.90	-	0.24%	4,196,300
10/19/2001	\$41.59	-	-0.74%	3,905,500
10/22/2001	\$42.76	-	2.77%	5,941,600
10/23/2001	\$38.39	-	-10.78%	22,797,900
10/24/2001	\$39.61	-	3.13%	15,942,700
10/25/2001	\$39.55	-	-0.15%	10,879,300
10/26/2001	\$39.34	-	-0.53%	9,652,300
10/29/2001	\$40.09	-	1.89%	8,786,400
10/30/2001	\$40.20	-	0.27%	7,081,800
10/31/2001	\$40.52	-	0.79%	7,177,900
11/1/2001	\$40.88	-	0.88%	5,173,400
11/2/2001	\$40.85	-	-0.07%	4,547,400

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**Source:** CRSP



## Exhibit-5

### Pharmacia Corp. Bid-Ask Spread

17 April 2000 through 3 August 2001

Date	PHA Closing Bid	PHA Closing Ask	% Spread	\$ Spread
4/17/2000	\$53.88	\$54.38	0.92%	\$0.50
4/18/2000	NA	NA	NA	NA
4/19/2000	NA	NA	NA	NA
4/20/2000	NA	NA	NA	NA
4/24/2000	\$57.88	\$58.19	0.54%	\$0.31
4/25/2000	\$53.81	\$54.13	0.58%	\$0.31
4/26/2000	\$52.75	\$53.06	0.59%	\$0.31
4/27/2000	\$52.63	\$53.00	0.71%	\$0.38
4/28/2000	\$48.88	\$50.13	2.53%	\$1.25
5/1/2000	\$49.38	\$49.75	0.76%	\$0.38
5/2/2000	\$49.81	\$49.94	0.25%	\$0.13
5/3/2000	\$50.75	\$51.13	0.74%	\$0.38
5/4/2000	\$52.25	\$52.63	0.72%	\$0.38
5/5/2000	\$53.75	\$54.13	0.70%	\$0.38
5/8/2000	\$55.38	\$55.75	0.67%	\$0.38
5/9/2000	\$55.38	\$55.75	0.67%	\$0.38
5/10/2000	\$53.88	\$54.25	0.69%	\$0.38
5/11/2000	\$54.19	\$54.56	0.69%	\$0.38
5/12/2000	\$53.38	\$53.69	0.58%	\$0.31
5/15/2000	\$54.94	\$55.31	0.68%	\$0.38
5/16/2000	\$53.56	\$53.88	0.58%	\$0.31
5/17/2000	\$52.69	\$53.06	0.71%	\$0.38
5/18/2000	\$52.25	\$52.63	0.72%	\$0.38
5/19/2000	\$54.69	\$55.06	0.68%	\$0.38
5/22/2000	\$53.00	\$53.38	0.71%	\$0.38
5/23/2000	\$53.25	\$53.63	0.70%	\$0.38
5/24/2000	\$51.63	\$51.94	0.60%	\$0.31
5/25/2000	\$52.00	\$52.38	0.72%	\$0.38
5/26/2000	\$51.63	\$52.06	0.84%	\$0.44
5/30/2000	\$50.31	\$50.69	0.74%	\$0.38
5/31/2000	\$51.44	\$52.44	1.93%	\$1.00
6/1/2000	\$51.81	\$51.94	0.24%	\$0.13
6/2/2000	\$49.06	\$49.44	0.76%	\$0.38
6/5/2000	\$49.81	\$50.13	0.63%	\$0.31
6/6/2000	\$48.94	\$49.25	0.64%	\$0.31
6/7/2000	\$50.38	\$50.75	0.74%	\$0.38

## Exhibit-5

### Pharmacia Corp. Bid-Ask Spread

17 April 2000 through 3 August 2001

Date	PHA Closing Bid	PHA Closing Ask	% Spread	\$ Spread
6/8/2000	\$49.94	\$50.25	0.62%	\$0.31
6/9/2000	\$51.88	\$52.44	1.08%	\$0.56
6/12/2000	\$51.63	\$52.19	1.08%	\$0.56
6/13/2000	\$52.94	\$53.13	0.35%	\$0.19
6/14/2000	\$54.56	\$54.81	0.46%	\$0.25
6/15/2000	\$55.63	\$55.94	0.56%	\$0.31
6/16/2000	\$55.94	\$56.25	0.56%	\$0.31
6/19/2000	\$56.31	\$56.50	0.33%	\$0.19
6/20/2000	\$56.25	\$56.56	0.55%	\$0.31
6/21/2000	\$55.13	\$55.38	0.45%	\$0.25
6/22/2000	\$51.31	\$51.81	0.97%	\$0.50
6/23/2000	\$53.00	\$53.19	0.35%	\$0.19
6/26/2000	\$53.19	\$53.38	0.35%	\$0.19
6/27/2000	\$53.38	\$53.69	0.58%	\$0.31
6/28/2000	\$51.63	\$51.94	0.60%	\$0.31
6/29/2000	\$50.38	\$50.50	0.25%	\$0.13
6/30/2000	\$51.13	\$51.81	1.34%	\$0.69
7/3/2000	\$52.50	\$52.81	0.59%	\$0.31
7/5/2000	\$53.38	\$53.69	0.58%	\$0.31
7/6/2000	\$54.00	\$54.25	0.46%	\$0.25
7/7/2000	\$54.69	\$54.88	0.34%	\$0.19
7/10/2000	\$55.94	\$56.13	0.33%	\$0.19
7/11/2000	\$57.19	\$57.25	0.11%	\$0.06
7/12/2000	\$56.56	\$56.88	0.55%	\$0.31
7/13/2000	\$55.44	\$55.56	0.23%	\$0.13
7/14/2000	\$55.50	\$55.69	0.34%	\$0.19
7/17/2000	\$55.69	\$55.94	0.45%	\$0.25
7/18/2000	\$55.00	\$55.19	0.34%	\$0.19
7/19/2000	\$53.50	\$53.75	0.47%	\$0.25
7/20/2000	\$52.50	\$52.69	0.36%	\$0.19
7/21/2000	\$51.88	\$52.06	0.36%	\$0.19
7/24/2000	\$51.75	\$52.50	1.44%	\$0.75
7/25/2000	\$55.50	\$55.81	0.56%	\$0.31
7/26/2000	\$55.50	\$55.94	0.79%	\$0.44
7/27/2000	\$55.56	\$56.00	0.78%	\$0.44
7/28/2000	\$55.75	\$56.00	0.45%	\$0.25

## Exhibit-5

### Pharmacia Corp. Bid-Ask Spread

17 April 2000 through 3 August 2001

Date	PHA Closing Bid	PHA Closing Ask	% Spread	\$ Spread
7/31/2000	\$54.88	\$55.06	0.34%	\$0.19
8/1/2000	\$55.50	\$55.75	0.45%	\$0.25
8/2/2000	\$57.38	\$57.69	0.54%	\$0.31
8/3/2000	\$56.75	\$57.13	0.66%	\$0.38
8/4/2000	\$56.63	\$56.81	0.33%	\$0.19
8/7/2000	\$57.31	\$57.63	0.54%	\$0.31
8/8/2000	\$58.88	\$59.00	0.21%	\$0.13
8/9/2000	\$57.50	\$57.69	0.33%	\$0.19
8/10/2000	\$55.63	\$55.75	0.22%	\$0.13
8/11/2000	\$56.19	\$56.31	0.22%	\$0.13
8/14/2000	\$56.06	\$56.25	0.33%	\$0.19
8/15/2000	\$56.75	\$56.94	0.33%	\$0.19
8/16/2000	\$57.69	\$57.88	0.32%	\$0.19
8/17/2000	\$59.31	\$59.63	0.53%	\$0.31
8/18/2000	\$57.81	\$58.00	0.32%	\$0.19
8/21/2000	\$57.63	\$57.88	0.43%	\$0.25
8/22/2000	\$57.38	\$57.56	0.33%	\$0.19
8/23/2000	\$57.44	\$57.56	0.22%	\$0.13
8/24/2000	\$58.69	\$58.88	0.32%	\$0.19
8/25/2000	\$58.81	\$59.06	0.42%	\$0.25
8/28/2000	\$58.00	\$58.31	0.54%	\$0.31
8/29/2000	\$58.81	\$58.94	0.21%	\$0.13
8/30/2000	\$58.56	\$58.69	0.21%	\$0.13
8/31/2000	\$58.31	\$58.44	0.21%	\$0.13
9/1/2000	\$58.25	\$58.38	0.21%	\$0.13
9/5/2000	\$56.31	\$56.56	0.44%	\$0.25
9/6/2000	\$55.81	\$56.00	0.34%	\$0.19
9/7/2000	\$56.50	\$56.69	0.33%	\$0.19
9/8/2000	\$54.75	\$54.94	0.34%	\$0.19
9/11/2000	\$54.38	\$54.50	0.23%	\$0.13
9/12/2000	\$54.38	\$54.50	0.23%	\$0.13
9/13/2000	\$55.13	\$55.25	0.23%	\$0.13
9/14/2000	\$54.63	\$54.81	0.34%	\$0.19
9/15/2000	\$53.44	\$53.69	0.47%	\$0.25
9/18/2000	\$52.88	\$53.00	0.24%	\$0.13
9/19/2000	\$53.81	\$54.06	0.46%	\$0.25

## Exhibit-5

### Pharmacia Corp. Bid-Ask Spread

17 April 2000 through 3 August 2001

<b>Date</b>	<b>PHA Closing Bid</b>	<b>PHA Closing Ask</b>	<b>% Spread</b>	<b>\$ Spread</b>
9/20/2000	\$54.13	\$54.38	0.46%	\$0.25
9/21/2000	\$55.94	\$56.13	0.33%	\$0.19
9/22/2000	\$58.81	\$59.00	0.32%	\$0.19
9/25/2000	\$58.81	\$59.00	0.32%	\$0.19
9/26/2000	\$57.94	\$58.06	0.22%	\$0.13
9/27/2000	\$58.44	\$58.56	0.21%	\$0.13
9/28/2000	\$59.94	\$60.06	0.21%	\$0.13
9/29/2000	\$60.06	\$60.38	0.52%	\$0.31
10/2/2000	\$57.06	\$58.06	1.74%	\$1.00
10/3/2000	\$57.19	\$58.19	1.73%	\$1.00
10/4/2000	\$56.56	\$57.56	1.75%	\$1.00
10/5/2000	\$57.00	\$58.00	1.74%	\$1.00
10/6/2000	\$56.38	\$57.38	1.76%	\$1.00
10/9/2000	\$55.81	\$56.81	1.78%	\$1.00
10/10/2000	\$57.31	\$58.31	1.73%	\$1.00
10/11/2000	\$57.31	\$58.31	1.73%	\$1.00
10/12/2000	\$57.00	\$58.00	1.74%	\$1.00
10/13/2000	\$54.44	\$55.44	1.82%	\$1.00
10/16/2000	\$54.69	\$55.69	1.81%	\$1.00
10/17/2000	\$55.94	\$56.94	1.77%	\$1.00
10/18/2000	\$54.50	\$55.50	1.82%	\$1.00
10/19/2000	\$53.06	\$54.06	1.87%	\$1.00
10/20/2000	\$50.25	\$51.25	1.97%	\$1.00
10/23/2000	\$53.38	\$54.38	1.86%	\$1.00
10/24/2000	\$54.50	\$55.50	1.82%	\$1.00
10/25/2000	\$56.38	\$57.38	1.76%	\$1.00
10/26/2000	\$55.31	\$56.31	1.79%	\$1.00
10/27/2000	\$54.13	\$55.13	1.83%	\$1.00
10/30/2000	\$52.13	\$53.13	1.90%	\$1.00
10/31/2000	\$54.50	\$55.50	1.82%	\$1.00
11/1/2000	\$56.94	\$57.94	1.74%	\$1.00
11/2/2000	\$57.50	\$58.50	1.72%	\$1.00
11/3/2000	\$55.75	\$56.75	1.78%	\$1.00
11/6/2000	\$57.06	\$58.06	1.74%	\$1.00
11/7/2000	\$57.00	\$58.00	1.74%	\$1.00
11/8/2000	\$58.94	\$59.94	1.68%	\$1.00

## Exhibit-5

### Pharmacia Corp. Bid-Ask Spread

17 April 2000 through 3 August 2001

Date	PHA Closing Bid	PHA Closing Ask	% Spread	\$ Spread
11/9/2000	\$58.75	\$59.75	1.69%	\$1.00
11/10/2000	\$58.75	\$59.75	1.69%	\$1.00
11/13/2000	\$56.75	\$57.75	1.75%	\$1.00
11/14/2000	\$58.25	\$59.25	1.70%	\$1.00
11/15/2000	\$57.75	\$58.75	1.72%	\$1.00
11/16/2000	\$56.50	\$57.50	1.75%	\$1.00
11/17/2000	\$59.31	\$60.31	1.67%	\$1.00
11/20/2000	\$59.00	\$60.00	1.68%	\$1.00
11/21/2000	\$59.13	\$60.13	1.68%	\$1.00
11/22/2000	\$57.56	\$58.56	1.72%	\$1.00
11/24/2000	\$57.19	\$58.19	1.73%	\$1.00
11/27/2000	\$59.00	\$60.00	1.68%	\$1.00
11/28/2000	\$58.75	\$59.75	1.69%	\$1.00
11/29/2000	\$60.44	\$61.44	1.64%	\$1.00
11/30/2000	\$60.50	\$61.50	1.64%	\$1.00
12/1/2000	\$57.00	\$58.00	1.74%	\$1.00
12/4/2000	\$58.56	\$59.56	1.69%	\$1.00
12/5/2000	\$59.25	\$60.25	1.67%	\$1.00
12/6/2000	\$57.25	\$58.25	1.73%	\$1.00
12/7/2000	\$57.50	\$58.50	1.72%	\$1.00
12/8/2000	\$58.50	\$59.50	1.69%	\$1.00
12/11/2000	\$58.50	\$58.88	0.64%	\$0.38
12/12/2000	\$57.31	\$58.31	1.73%	\$1.00
12/13/2000	\$58.06	\$59.06	1.71%	\$1.00
12/14/2000	\$58.81	\$59.81	1.69%	\$1.00
12/15/2000	\$59.13	\$60.13	1.68%	\$1.00
12/18/2000	\$58.88	\$59.88	1.68%	\$1.00
12/19/2000	\$57.50	\$58.50	1.72%	\$1.00
12/20/2000	\$59.44	\$60.44	1.67%	\$1.00
12/21/2000	\$57.56	\$58.56	1.72%	\$1.00
12/22/2000	\$56.94	\$57.94	1.74%	\$1.00
12/26/2000	\$58.13	\$59.00	1.49%	\$0.88
12/27/2000	\$59.50	\$60.50	1.67%	\$1.00
12/28/2000	\$60.44	\$61.44	1.64%	\$1.00
12/29/2000	\$60.50	\$61.50	1.64%	\$1.00
1/2/2001	\$59.50	\$60.50	1.67%	\$1.00

## Exhibit-5

### Pharmacia Corp. Bid-Ask Spread

17 April 2000 through 3 August 2001

Date	PHA Closing Bid	PHA Closing Ask	% Spread	\$ Spread
1/3/2001	\$56.50	\$57.50	1.75%	\$1.00
1/4/2001	\$54.81	\$55.81	1.81%	\$1.00
1/5/2001	\$55.88	\$56.88	1.77%	\$1.00
1/8/2001	\$56.00	\$57.00	1.77%	\$1.00
1/9/2001	\$55.19	\$56.19	1.80%	\$1.00
1/10/2001	\$55.00	\$56.00	1.80%	\$1.00
1/11/2001	\$54.44	\$55.44	1.82%	\$1.00
1/12/2001	\$55.00	\$56.00	1.80%	\$1.00
1/16/2001	\$55.81	\$56.81	1.78%	\$1.00
1/17/2001	\$55.38	\$56.38	1.79%	\$1.00
1/18/2001	\$56.31	\$57.31	1.76%	\$1.00
1/19/2001	\$55.75	\$56.75	1.78%	\$1.00
1/22/2001	\$55.69	\$56.69	1.78%	\$1.00
1/23/2001	\$55.06	\$56.06	1.80%	\$1.00
1/24/2001	\$54.88	\$55.88	1.81%	\$1.00
1/25/2001	\$55.00	\$56.00	1.80%	\$1.00
1/26/2001	\$55.31	\$56.31	1.79%	\$1.00
1/29/2001	\$54.90	\$55.90	1.81%	\$1.00
1/30/2001	\$54.68	\$55.68	1.81%	\$1.00
1/31/2001	\$55.51	\$56.51	1.79%	\$1.00
2/1/2001	\$56.58	\$57.58	1.75%	\$1.00
2/2/2001	\$57.31	\$58.31	1.73%	\$1.00
2/5/2001	\$57.78	\$58.78	1.72%	\$1.00
2/6/2001	\$57.15	\$58.15	1.73%	\$1.00
2/7/2001	\$55.63	\$56.63	1.78%	\$1.00
2/8/2001	\$53.00	\$53.50	0.94%	\$0.50
2/9/2001	\$53.50	\$54.50	1.85%	\$1.00
2/12/2001	\$53.73	\$54.73	1.84%	\$1.00
2/13/2001	\$51.13	\$52.00	1.69%	\$0.87
2/14/2001	\$51.40	\$52.40	1.93%	\$1.00
2/15/2001	\$51.52	\$52.52	1.92%	\$1.00
2/16/2001	\$50.66	\$51.66	1.95%	\$1.00
2/20/2001	\$49.45	\$50.45	2.00%	\$1.00
2/21/2001	\$48.35	\$49.35	2.05%	\$1.00
2/22/2001	\$48.75	\$49.75	2.03%	\$1.00
2/23/2001	\$48.55	\$49.55	2.04%	\$1.00

**Exhibit-5**

**Pharmacia Corp. Bid-Ask Spread**

17 April 2000 through 3 August 2001

<b>Date</b>	<b>PHA Closing Bid</b>	<b>PHA Closing Ask</b>	<b>% Spread</b>	<b>\$ Spread</b>
2/26/2001	\$48.90	\$49.90	2.02%	\$1.00
2/27/2001	\$49.75	\$51.00	2.48%	\$1.25
2/28/2001	\$51.20	\$52.20	1.93%	\$1.00
3/1/2001	\$51.47	\$52.47	1.92%	\$1.00
3/2/2001	\$52.29	\$53.29	1.89%	\$1.00
3/5/2001	\$53.55	\$54.55	1.85%	\$1.00
3/6/2001	\$52.35	\$53.35	1.89%	\$1.00
3/7/2001	\$50.51	\$51.51	1.96%	\$1.00
3/8/2001	\$50.24	\$51.24	1.97%	\$1.00
3/9/2001	\$50.69	\$51.69	1.95%	\$1.00
3/12/2001	\$49.72	\$51.00	2.54%	\$1.28
3/13/2001	\$48.60	\$49.60	2.04%	\$1.00
3/14/2001	\$47.30	\$48.30	2.09%	\$1.00
3/15/2001	\$46.96	\$47.96	2.11%	\$1.00
3/16/2001	\$44.68	\$45.68	2.21%	\$1.00
3/19/2001	\$47.17	\$47.66	1.03%	\$0.49
3/20/2001	\$46.62	\$47.62	2.12%	\$1.00
3/21/2001	\$46.08	\$47.08	2.15%	\$1.00
3/22/2001	\$43.50	\$44.50	2.27%	\$1.00
3/23/2001	\$46.49	\$47.49	2.13%	\$1.00
3/26/2001	\$47.78	\$48.78	2.07%	\$1.00
3/27/2001	\$49.10	\$50.10	2.02%	\$1.00
3/28/2001	\$49.30	\$50.30	2.01%	\$1.00
3/29/2001	\$49.37	\$50.37	2.01%	\$1.00
3/30/2001	\$49.87	\$50.87	1.99%	\$1.00
4/2/2001	\$48.75	\$49.75	2.03%	\$1.00
4/3/2001	\$48.26	\$49.26	2.05%	\$1.00
4/4/2001	\$48.73	\$49.73	2.03%	\$1.00
4/5/2001	\$50.54	\$51.54	1.96%	\$1.00
4/6/2001	\$50.15	\$51.15	1.97%	\$1.00
4/9/2001	\$51.75	\$52.75	1.91%	\$1.00
4/10/2001	\$50.70	\$51.70	1.95%	\$1.00
4/11/2001	\$49.61	\$50.61	2.00%	\$1.00
4/12/2001	\$50.20	\$51.20	1.97%	\$1.00
4/16/2001	\$49.95	\$50.95	1.98%	\$1.00
4/17/2001	\$51.58	\$52.58	1.92%	\$1.00

## Exhibit-5

### Pharmacia Corp. Bid-Ask Spread

17 April 2000 through 3 August 2001

<b>Date</b>	<b>PHA Closing Bid</b>	<b>PHA Closing Ask</b>	<b>% Spread</b>	<b>\$ Spread</b>
4/18/2001	\$50.25	\$51.25	1.97%	\$1.00
4/19/2001	\$49.58	\$50.50	1.84%	\$0.92
4/20/2001	\$48.05	\$50.00	3.98%	\$1.95
4/23/2001	NA	NA	NA	NA
4/24/2001	\$47.51	\$48.51	2.08%	\$1.00
4/25/2001	\$48.60	\$49.60	2.04%	\$1.00
4/26/2001	\$51.01	\$52.01	1.94%	\$1.00
4/27/2001	\$51.75	\$52.75	1.91%	\$1.00
4/30/2001	\$51.76	\$52.76	1.91%	\$1.00
5/1/2001	\$51.22	\$52.22	1.93%	\$1.00
5/2/2001	\$50.50	\$51.50	1.96%	\$1.00
5/3/2001	\$49.50	\$50.50	2.00%	\$1.00
5/4/2001	\$49.50	\$50.50	2.00%	\$1.00
5/7/2001	\$48.45	\$49.45	2.04%	\$1.00
5/8/2001	\$47.70	\$48.70	2.07%	\$1.00
5/9/2001	\$46.99	\$47.99	2.11%	\$1.00
5/10/2001	\$46.48	\$47.48	2.13%	\$1.00
5/11/2001	\$45.65	\$46.65	2.17%	\$1.00
5/14/2001	\$45.78	\$46.78	2.16%	\$1.00
5/15/2001	\$45.49	\$46.49	2.17%	\$1.00
5/16/2001	\$47.88	\$48.88	2.07%	\$1.00
5/17/2001	\$48.99	\$49.99	2.02%	\$1.00
5/18/2001	\$48.00	\$49.00	2.06%	\$1.00
5/21/2001	\$49.96	\$50.13	0.34%	\$0.17
5/22/2001	\$49.42	\$49.64	0.44%	\$0.22
5/23/2001	\$48.57	\$48.84	0.55%	\$0.27
5/24/2001	\$48.63	\$48.79	0.33%	\$0.16
5/25/2001	\$48.50	\$48.67	0.35%	\$0.17
5/29/2001	\$48.00	\$48.05	0.10%	\$0.05
5/30/2001	\$48.17	\$48.29	0.25%	\$0.12
5/31/2001	\$48.45	\$48.67	0.45%	\$0.22
6/1/2001	\$49.22	\$49.46	0.49%	\$0.24
6/4/2001	\$49.50	\$49.77	0.54%	\$0.27
6/5/2001	\$49.47	\$49.71	0.48%	\$0.24
6/6/2001	\$49.22	\$49.46	0.49%	\$0.24
6/7/2001	\$49.65	\$49.93	0.56%	\$0.28



## Exhibit-5

### Pharmacia Corp. Bid-Ask Spread

17 April 2000 through 3 August 2001

Date	PHA Closing Bid	PHA Closing Ask	% Spread	\$ Spread
6/8/2001	\$49.55	\$49.81	0.52%	\$0.26
6/11/2001	\$48.95	\$49.16	0.43%	\$0.21
6/12/2001	\$48.81	\$49.10	0.59%	\$0.29
6/13/2001	\$48.60	\$48.90	0.62%	\$0.30
6/14/2001	\$48.03	\$48.25	0.46%	\$0.22
6/15/2001	\$48.70	\$48.91	0.43%	\$0.21
6/18/2001	\$49.01	\$49.24	0.47%	\$0.23
6/19/2001	\$49.40	\$49.67	0.55%	\$0.27
6/20/2001	\$50.63	\$50.86	0.45%	\$0.23
6/21/2001	\$51.35	\$51.65	0.58%	\$0.30
6/22/2001	\$48.67	\$48.90	0.47%	\$0.23
6/25/2001	\$48.70	\$48.96	0.53%	\$0.26
6/26/2001	\$48.31	\$48.53	0.45%	\$0.22
6/27/2001	\$47.11	\$47.33	0.47%	\$0.22
6/28/2001	\$47.01	\$47.24	0.49%	\$0.23
6/29/2001	\$45.75	\$46.10	0.76%	\$0.35
7/2/2001	\$46.47	\$46.69	0.47%	\$0.22
7/3/2001	\$46.42	\$46.70	0.60%	\$0.28
7/5/2001	\$46.36	\$46.61	0.54%	\$0.25
7/6/2001	\$45.97	\$46.17	0.43%	\$0.20
7/9/2001	\$46.70	\$46.92	0.47%	\$0.22
7/10/2001	\$46.84	\$47.05	0.45%	\$0.21
7/11/2001	\$46.56	\$46.81	0.54%	\$0.25
7/12/2001	\$46.11	\$46.34	0.50%	\$0.23
7/13/2001	\$46.73	\$46.95	0.47%	\$0.22
7/16/2001	\$42.74	\$42.95	0.49%	\$0.21
7/17/2001	\$42.47	\$42.71	0.56%	\$0.24
7/18/2001	\$43.05	\$43.30	0.58%	\$0.25
7/19/2001	\$43.24	\$43.46	0.51%	\$0.22
7/20/2001	\$43.51	\$43.75	0.55%	\$0.24
7/23/2001	\$43.30	\$43.52	0.51%	\$0.22
7/24/2001	\$41.80	\$42.10	0.72%	\$0.30
7/25/2001	\$41.97	\$42.23	0.62%	\$0.26
7/26/2001	\$41.73	\$41.97	0.57%	\$0.24
7/27/2001	\$42.02	\$42.30	0.66%	\$0.28
7/30/2001	\$43.14	\$43.37	0.53%	\$0.23

**Exhibit-5**

**Pharmacia Corp. Bid-Ask Spread**

17 April 2000 through 3 August 2001

<b>Date</b>	<b>PHA Closing Bid</b>	<b>PHA Closing Ask</b>	<b>% Spread</b>	<b>\$ Spread</b>
7/31/2001	\$44.44	\$44.69	0.56%	\$0.25
8/1/2001	\$44.35	\$44.53	0.41%	\$0.18
8/2/2001	\$43.74	\$43.97	0.52%	\$0.23
8/3/2001	\$43.89	\$44.09	0.45%	\$0.20
<b>Average</b>	<b>\$52.82</b>	<b>\$53.44</b>	<b>1.17%</b>	<b>\$0.62</b>

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**Source:** CRSP

## Exhibit-6

### Pharmacia Pharmaceuticals Stock Price

(Pharmacia Stock Price Less Per Share Value of New Monsanto Holdings)

18 October 2000 through 18 October 2001

<b>Date</b>	<b>PHA Share Price</b>	<b>PHA Shares Outstanding</b>	<b>MON Share Price</b>	<b>MON Shares Owned by PHA</b>	<b>Value of MON per PHA Share</b>	<b>PHA Adjusted for MON</b>
10/18/2000	\$55.00	1,269,325	\$21.50	220,000	\$3.73	\$51.27
10/19/2000	\$53.56	1,269,325	\$24.00	220,000	\$4.16	\$49.40
10/20/2000	\$50.75	1,269,325	\$23.13	220,000	\$4.01	\$46.74
10/23/2000	\$53.88	1,269,325	\$22.00	220,000	\$3.81	\$50.06
10/24/2000	\$55.00	1,269,325	\$22.13	220,000	\$3.83	\$51.17
10/25/2000	\$56.88	1,269,325	\$22.94	220,000	\$3.98	\$52.90
10/26/2000	\$55.81	1,269,325	\$23.44	220,000	\$4.06	\$51.75
10/27/2000	\$54.63	1,269,325	\$23.94	220,000	\$4.15	\$50.48
10/30/2000	\$52.63	1,269,325	\$24.63	220,000	\$4.27	\$48.36
10/31/2000	\$55.00	1,269,325	\$25.50	220,000	\$4.42	\$50.58
11/1/2000	\$57.44	1,269,325	\$23.75	220,000	\$4.12	\$53.32
11/2/2000	\$58.00	1,269,325	\$23.06	220,000	\$4.00	\$54.00
11/3/2000	\$56.25	1,269,325	\$22.94	220,000	\$3.98	\$52.27
11/6/2000	\$57.56	1,269,325	\$23.31	220,000	\$4.04	\$53.52
11/7/2000	\$57.50	1,269,325	\$23.25	220,000	\$4.03	\$53.47
11/8/2000	\$59.44	1,269,325	\$23.06	220,000	\$4.00	\$55.44
11/9/2000	\$59.25	1,269,325	\$23.00	220,000	\$3.99	\$55.26
11/10/2000	\$59.25	1,269,325	\$22.50	220,000	\$3.90	\$55.35
11/13/2000	\$57.25	1,269,325	\$22.56	220,000	\$3.91	\$53.34
11/14/2000	\$58.75	1,269,325	\$23.44	220,000	\$4.06	\$54.69
11/15/2000	\$58.25	1,269,325	\$24.38	220,000	\$4.22	\$54.03
11/16/2000	\$57.00	1,269,325	\$23.81	220,000	\$4.13	\$52.87
11/17/2000	\$59.81	1,269,325	\$24.13	220,000	\$4.18	\$55.63
11/20/2000	\$59.50	1,269,325	\$23.31	220,000	\$4.04	\$55.46
11/21/2000	\$59.63	1,269,325	\$23.13	220,000	\$4.01	\$55.62
11/22/2000	\$58.06	1,269,325	\$22.81	220,000	\$3.95	\$54.11
11/24/2000	\$57.69	1,269,325	\$23.44	220,000	\$4.06	\$53.63
11/27/2000	\$59.50	1,269,325	\$23.56	220,000	\$4.08	\$55.42
11/28/2000	\$59.25	1,269,325	\$23.88	220,000	\$4.14	\$55.11
11/29/2000	\$60.94	1,269,325	\$25.00	220,000	\$4.33	\$56.60
11/30/2000	\$61.00	1,288,998	\$25.06	220,000	\$4.28	\$56.72
12/1/2000	\$57.50	1,288,998	\$24.81	220,000	\$4.23	\$53.27
12/4/2000	\$59.06	1,288,998	\$25.25	220,000	\$4.31	\$54.75

## Exhibit-6

### Pharmacia Pharmaceuticals Stock Price

(Pharmacia Stock Price Less Per Share Value of New Monsanto Holdings)

18 October 2000 through 18 October 2001

Date	PHA Share Price	PHA Shares Outstanding	MON Share Price	MON Shares Owned by PHA	Value of MON per PHA Share	PHA Adjusted for MON
12/5/2000	\$59.75	1,288,998	\$25.25	220,000	\$4.31	\$55.44
12/6/2000	\$57.75	1,288,998	\$25.31	220,000	\$4.32	\$53.43
12/7/2000	\$58.00	1,288,998	\$24.94	220,000	\$4.26	\$53.74
12/8/2000	\$59.00	1,288,998	\$24.88	220,000	\$4.25	\$54.75
12/11/2000	\$58.69	1,288,998	\$25.69	220,000	\$4.38	\$54.30
12/12/2000	\$57.81	1,288,998	\$25.13	220,000	\$4.29	\$53.52
12/13/2000	\$58.56	1,288,998	\$25.25	220,000	\$4.31	\$54.25
12/14/2000	\$59.31	1,288,998	\$25.38	220,000	\$4.33	\$54.98
12/15/2000	\$59.63	1,288,998	\$25.38	220,000	\$4.33	\$55.29
12/18/2000	\$59.38	1,288,998	\$25.63	220,000	\$4.37	\$55.00
12/19/2000	\$58.00	1,288,998	\$25.38	220,000	\$4.33	\$53.67
12/20/2000	\$59.94	1,288,998	\$25.06	220,000	\$4.28	\$55.66
12/21/2000	\$58.06	1,288,998	\$23.94	220,000	\$4.09	\$53.98
12/22/2000	\$57.44	1,288,998	\$23.69	220,000	\$4.04	\$53.39
12/26/2000	\$58.63	1,288,998	\$24.06	220,000	\$4.11	\$54.52
12/27/2000	\$60.00	1,288,998	\$25.19	220,000	\$4.30	\$55.70
12/28/2000	\$60.94	1,288,998	\$26.19	220,000	\$4.47	\$56.47
12/29/2000	\$61.00	1,288,998	\$27.06	220,000	\$4.62	\$56.38
1/2/2001	\$60.00	1,288,998	\$28.25	220,000	\$4.82	\$55.18
1/3/2001	\$57.00	1,288,998	\$31.38	220,000	\$5.35	\$51.65
1/4/2001	\$55.31	1,288,998	\$30.50	220,000	\$5.21	\$50.11
1/5/2001	\$56.38	1,288,998	\$29.69	220,000	\$5.07	\$51.31
1/8/2001	\$56.50	1,288,998	\$29.69	220,000	\$5.07	\$51.43
1/9/2001	\$55.69	1,288,998	\$29.38	220,000	\$5.01	\$50.67
1/10/2001	\$55.50	1,288,998	\$29.63	220,000	\$5.06	\$50.44
1/11/2001	\$54.94	1,288,998	\$29.25	220,000	\$4.99	\$49.95
1/12/2001	\$55.50	1,288,998	\$30.00	220,000	\$5.12	\$50.38
1/16/2001	\$56.31	1,288,998	\$30.19	220,000	\$5.15	\$51.16
1/17/2001	\$55.88	1,288,998	\$30.50	220,000	\$5.21	\$50.67
1/18/2001	\$56.81	1,288,998	\$30.81	220,000	\$5.26	\$51.55
1/19/2001	\$56.25	1,288,998	\$29.13	220,000	\$4.97	\$51.28
1/22/2001	\$56.19	1,288,998	\$28.81	220,000	\$4.92	\$51.27
1/23/2001	\$55.56	1,288,998	\$28.50	220,000	\$4.86	\$50.70

## Exhibit-6

### Pharmacia Pharmaceuticals Stock Price

(Pharmacia Stock Price Less Per Share Value of New Monsanto Holdings)

18 October 2000 through 18 October 2001

Date	PHA Share Price	PHA Shares Outstanding	MON Share Price	MON Shares Owned by PHA	Value of MON per PHA Share	PHA Adjusted for MON
1/24/2001	\$55.38	1,288,998	\$28.94	220,000	\$4.94	\$50.44
1/25/2001	\$55.50	1,288,998	\$29.31	220,000	\$5.00	\$50.50
1/26/2001	\$55.81	1,288,998	\$30.19	220,000	\$5.15	\$50.66
1/29/2001	\$55.40	1,288,998	\$30.85	220,000	\$5.27	\$50.13
1/30/2001	\$55.18	1,288,998	\$31.03	220,000	\$5.30	\$49.88
1/31/2001	\$56.02	1,288,998	\$31.51	220,000	\$5.38	\$50.64
2/1/2001	\$57.08	1,288,998	\$31.01	220,000	\$5.29	\$51.79
2/2/2001	\$57.81	1,288,998	\$30.00	220,000	\$5.12	\$52.69
2/5/2001	\$58.28	1,288,998	\$30.00	220,000	\$5.12	\$53.16
2/6/2001	\$57.65	1,288,998	\$30.71	220,000	\$5.24	\$52.41
2/7/2001	\$56.13	1,288,998	\$31.32	220,000	\$5.35	\$50.78
2/8/2001	\$53.00	1,288,998	\$32.00	220,000	\$5.46	\$47.54
2/9/2001	\$54.00	1,288,998	\$33.37	220,000	\$5.70	\$48.30
2/12/2001	\$54.23	1,288,998	\$34.40	220,000	\$5.87	\$48.36
2/13/2001	\$51.63	1,288,998	\$35.50	220,000	\$6.06	\$45.57
2/14/2001	\$51.90	1,288,998	\$33.98	220,000	\$5.80	\$46.10
2/15/2001	\$52.02	1,288,998	\$33.73	220,000	\$5.76	\$46.26
2/16/2001	\$51.16	1,288,998	\$31.78	220,000	\$5.42	\$45.74
2/20/2001	\$49.95	1,288,998	\$28.75	220,000	\$4.91	\$45.04
2/21/2001	\$48.85	1,288,998	\$29.90	220,000	\$5.10	\$43.75
2/22/2001	\$49.25	1,288,998	\$29.99	220,000	\$5.12	\$44.13
2/23/2001	\$49.05	1,288,998	\$28.20	220,000	\$4.81	\$44.24
2/26/2001	\$49.40	1,288,998	\$30.05	220,000	\$5.13	\$44.27
2/27/2001	\$50.25	1,288,998	\$29.90	220,000	\$5.10	\$45.15
2/28/2001	\$51.70	1,288,998	\$32.00	220,000	\$5.46	\$46.24
3/1/2001	\$51.97	1,288,998	\$32.35	220,000	\$5.52	\$46.45
3/2/2001	\$52.79	1,288,998	\$32.65	220,000	\$5.57	\$47.22
3/5/2001	\$54.05	1,288,998	\$33.62	220,000	\$5.74	\$48.31
3/6/2001	\$52.85	1,288,998	\$34.51	220,000	\$5.89	\$46.96
3/7/2001	\$51.01	1,288,998	\$33.90	220,000	\$5.79	\$45.22
3/8/2001	\$50.74	1,288,998	\$34.11	220,000	\$5.82	\$44.92
3/9/2001	\$51.19	1,288,998	\$33.48	220,000	\$5.71	\$45.48
3/12/2001	\$50.22	1,288,998	\$33.00	220,000	\$5.63	\$44.59

## Exhibit-6

### Pharmacia Pharmaceuticals Stock Price

(Pharmacia Stock Price Less Per Share Value of New Monsanto Holdings)

18 October 2000 through 18 October 2001

Date	PHA Share Price	PHA Shares Outstanding	MON Share Price	MON Shares Owned by PHA	Value of MON per PHA Share	PHA Adjusted for MON
3/13/2001	\$49.10	1,288,998	\$32.95	220,000	\$5.62	\$43.48
3/14/2001	\$47.80	1,288,998	\$32.60	220,000	\$5.56	\$42.24
3/15/2001	\$47.46	1,288,998	\$33.75	220,000	\$5.76	\$41.70
3/16/2001	\$45.18	1,288,998	\$33.68	220,000	\$5.75	\$39.43
3/19/2001	\$47.16	1,288,998	\$33.05	220,000	\$5.64	\$41.52
3/20/2001	\$47.12	1,288,998	\$33.05	220,000	\$5.64	\$41.48
3/21/2001	\$46.58	1,288,998	\$33.19	220,000	\$5.66	\$40.92
3/22/2001	\$44.00	1,288,998	\$33.01	220,000	\$5.63	\$38.37
3/23/2001	\$46.99	1,288,998	\$33.02	220,000	\$5.64	\$41.35
3/26/2001	\$48.28	1,288,998	\$34.00	220,000	\$5.80	\$42.48
3/27/2001	\$49.60	1,288,998	\$33.25	220,000	\$5.67	\$43.93
3/28/2001	\$49.80	1,288,998	\$33.10	220,000	\$5.65	\$44.15
3/29/2001	\$49.87	1,288,998	\$33.85	220,000	\$5.78	\$44.09
3/30/2001	\$50.37	1,299,800	\$35.46	220,000	\$6.00	\$44.37
4/2/2001	\$49.25	1,299,800	\$35.65	220,000	\$6.03	\$43.22
4/3/2001	\$48.76	1,299,800	\$35.02	220,000	\$5.93	\$42.83
4/4/2001	\$49.23	1,299,800	\$35.48	220,000	\$6.01	\$43.22
4/5/2001	\$51.04	1,299,800	\$36.80	220,000	\$6.23	\$44.81
4/6/2001	\$50.65	1,299,800	\$36.00	220,000	\$6.09	\$44.56
4/9/2001	\$52.25	1,299,800	\$35.99	220,000	\$6.09	\$46.16
4/10/2001	\$51.20	1,299,800	\$35.51	220,000	\$6.01	\$45.19
4/11/2001	\$50.11	1,299,800	\$34.85	220,000	\$5.90	\$44.21
4/12/2001	\$50.70	1,299,800	\$34.69	220,000	\$5.87	\$44.83
4/16/2001	\$50.45	1,299,800	\$34.55	220,000	\$5.85	\$44.60
4/17/2001	\$52.08	1,299,800	\$35.80	220,000	\$6.06	\$46.02
4/18/2001	\$50.75	1,299,800	\$34.51	220,000	\$5.84	\$44.91
4/19/2001	\$49.70	1,299,800	\$34.80	220,000	\$5.89	\$43.81
4/20/2001	\$48.55	1,299,800	\$35.10	220,000	\$5.94	\$42.61
4/23/2001	\$48.50	1,299,800	\$34.91	220,000	\$5.91	\$42.59
4/24/2001	\$48.01	1,299,800	\$33.59	220,000	\$5.69	\$42.32
4/25/2001	\$49.10	1,299,800	\$34.20	220,000	\$5.79	\$43.31
4/26/2001	\$51.51	1,299,800	\$31.93	220,000	\$5.40	\$46.11
4/27/2001	\$52.25	1,299,800	\$30.30	220,000	\$5.13	\$47.12

## Exhibit-6

### Pharmacia Pharmaceuticals Stock Price

(Pharmacia Stock Price Less Per Share Value of New Monsanto Holdings)

18 October 2000 through 18 October 2001

Date	PHA Share Price	PHA Shares Outstanding	MON Share Price	MON Shares Owned by PHA	Value of MON per PHA Share	PHA Adjusted for MON
4/30/2001	\$52.26	1,299,800	\$30.95	220,000	\$5.24	\$47.02
5/1/2001	\$51.72	1,299,800	\$32.00	220,000	\$5.42	\$46.30
5/2/2001	\$51.00	1,299,800	\$32.54	220,000	\$5.51	\$45.49
5/3/2001	\$50.00	1,299,800	\$32.62	220,000	\$5.52	\$44.48
5/4/2001	\$50.00	1,299,800	\$32.30	220,000	\$5.47	\$44.53
5/7/2001	\$48.95	1,299,800	\$32.20	220,000	\$5.45	\$43.50
5/8/2001	\$48.20	1,299,800	\$32.00	220,000	\$5.42	\$42.78
5/9/2001	\$47.49	1,299,800	\$32.20	220,000	\$5.45	\$42.04
5/10/2001	\$46.98	1,299,800	\$32.50	220,000	\$5.50	\$41.48
5/11/2001	\$46.15	1,299,800	\$33.27	220,000	\$5.63	\$40.52
5/14/2001	\$46.28	1,299,800	\$33.40	220,000	\$5.65	\$40.63
5/15/2001	\$45.99	1,299,800	\$34.58	220,000	\$5.85	\$40.14
5/16/2001	\$48.38	1,299,800	\$36.00	220,000	\$6.09	\$42.29
5/17/2001	\$49.49	1,299,800	\$36.40	220,000	\$6.16	\$43.33
5/18/2001	\$49.60	1,299,800	\$36.51	220,000	\$6.18	\$43.42
5/21/2001	\$50.02	1,299,800	\$36.30	220,000	\$6.14	\$43.88
5/22/2001	\$49.50	1,299,800	\$35.42	220,000	\$6.00	\$43.50
5/23/2001	\$48.74	1,299,800	\$35.25	220,000	\$5.97	\$42.77
5/24/2001	\$48.69	1,299,800	\$35.47	220,000	\$6.00	\$42.69
5/25/2001	\$48.56	1,299,800	\$35.60	220,000	\$6.03	\$42.53
5/29/2001	\$48.01	1,299,800	\$35.00	220,000	\$5.92	\$42.09
5/30/2001	\$48.25	1,299,800	\$34.85	220,000	\$5.90	\$42.35
5/31/2001	\$48.56	1,300,973	\$35.50	220,000	\$6.00	\$42.56
6/1/2001	\$49.35	1,300,973	\$35.82	220,000	\$6.06	\$43.29
6/4/2001	\$49.66	1,300,973	\$37.31	220,000	\$6.31	\$43.35
6/5/2001	\$49.60	1,300,973	\$36.40	220,000	\$6.16	\$43.44
6/6/2001	\$49.35	1,300,973	\$35.70	220,000	\$6.04	\$43.31
6/7/2001	\$49.81	1,300,973	\$35.95	220,000	\$6.08	\$43.73
6/8/2001	\$49.70	1,300,973	\$36.58	220,000	\$6.19	\$43.51
6/11/2001	\$49.06	1,300,973	\$36.30	220,000	\$6.14	\$42.92
6/12/2001	\$48.97	1,300,973	\$37.35	220,000	\$6.32	\$42.65
6/13/2001	\$48.75	1,300,973	\$38.12	220,000	\$6.45	\$42.30
6/14/2001	\$48.15	1,300,973	\$37.20	220,000	\$6.29	\$41.86

## Exhibit-6

### Pharmacia Pharmaceuticals Stock Price

(Pharmacia Stock Price Less Per Share Value of New Monsanto Holdings)

18 October 2000 through 18 October 2001

<b>Date</b>	<b>PHA Share Price</b>	<b>PHA Shares Outstanding</b>	<b>MON Share Price</b>	<b>MON Shares Owned by PHA</b>	<b>Value of MON per PHA Share</b>	<b>PHA Adjusted for MON</b>
6/15/2001	\$48.80	1,300,973	\$37.52	220,000	\$6.34	\$42.46
6/18/2001	\$49.19	1,300,973	\$37.54	220,000	\$6.35	\$42.84
6/19/2001	\$49.51	1,300,973	\$36.50	220,000	\$6.17	\$43.34
6/20/2001	\$50.75	1,300,973	\$36.74	220,000	\$6.21	\$44.54
6/21/2001	\$51.50	1,300,973	\$35.87	220,000	\$6.07	\$45.43
6/22/2001	\$48.79	1,300,973	\$35.29	220,000	\$5.97	\$42.82
6/25/2001	\$48.85	1,300,973	\$35.00	220,000	\$5.92	\$42.93
6/26/2001	\$48.43	1,300,973	\$35.00	220,000	\$5.92	\$42.51
6/27/2001	\$47.22	1,300,973	\$35.99	220,000	\$6.09	\$41.13
6/28/2001	\$47.12	1,300,973	\$36.05	220,000	\$6.10	\$41.02
6/29/2001	\$45.95	1,300,973	\$37.00	220,000	\$6.26	\$39.69
7/2/2001	\$46.58	1,300,973	\$38.00	220,000	\$6.43	\$40.15
7/3/2001	\$46.59	1,300,973	\$37.90	220,000	\$6.41	\$40.18
7/5/2001	\$46.50	1,300,973	\$37.20	220,000	\$6.29	\$40.21
7/6/2001	\$46.00	1,300,973	\$36.70	220,000	\$6.21	\$39.79
7/9/2001	\$46.81	1,300,973	\$36.47	220,000	\$6.17	\$40.64
7/10/2001	\$46.95	1,300,973	\$36.90	220,000	\$6.24	\$40.71
7/11/2001	\$46.70	1,300,973	\$36.91	220,000	\$6.24	\$40.46
7/12/2001	\$46.22	1,300,973	\$35.28	220,000	\$5.97	\$40.25
7/13/2001	\$46.85	1,300,973	\$33.37	220,000	\$5.64	\$41.21
7/16/2001	\$42.84	1,300,973	\$33.35	220,000	\$5.64	\$37.20
7/17/2001	\$42.60	1,300,973	\$34.02	220,000	\$5.75	\$36.85
7/18/2001	\$43.15	1,300,973	\$33.60	220,000	\$5.68	\$37.47
7/19/2001	\$43.35	1,300,973	\$33.70	220,000	\$5.70	\$37.65
7/20/2001	\$43.65	1,300,973	\$33.65	220,000	\$5.69	\$37.96
7/23/2001	\$43.41	1,300,973	\$33.60	220,000	\$5.68	\$37.73
7/24/2001	\$42.00	1,300,973	\$32.04	220,000	\$5.42	\$36.58
7/25/2001	\$42.12	1,300,973	\$34.26	220,000	\$5.79	\$36.33
7/26/2001	\$41.85	1,300,973	\$33.89	220,000	\$5.73	\$36.12
7/27/2001	\$42.12	1,300,973	\$33.84	220,000	\$5.72	\$36.40
7/30/2001	\$43.28	1,300,973	\$34.04	220,000	\$5.76	\$37.52
7/31/2001	\$44.62	1,300,973	\$35.20	220,000	\$5.95	\$38.67
8/1/2001	\$44.55	1,300,973	\$35.90	220,000	\$6.07	\$38.48



## Exhibit-6

### Pharmacia Pharmaceuticals Stock Price

(Pharmacia Stock Price Less Per Share Value of New Monsanto Holdings)

18 October 2000 through 18 October 2001

Date	PHA Share Price	PHA Shares Outstanding	MON Share Price	MON Shares Owned by PHA	Value of MON per PHA Share	PHA Adjusted for MON
8/2/2001	\$43.90	1,300,973	\$36.85	220,000	\$6.23	\$37.67
8/3/2001	\$44.00	1,300,973	\$37.00	220,000	\$6.26	\$37.74
8/6/2001	\$44.00	1,300,973	\$36.51	220,000	\$6.17	\$37.83
8/7/2001	\$45.10	1,300,973	\$35.07	220,000	\$5.93	\$39.17
8/8/2001	\$44.32	1,300,973	\$35.50	220,000	\$6.00	\$38.32
8/9/2001	\$44.35	1,300,973	\$33.50	220,000	\$5.66	\$38.69
8/10/2001	\$44.68	1,300,973	\$34.60	220,000	\$5.85	\$38.83
8/13/2001	\$45.35	1,300,973	\$34.95	220,000	\$5.91	\$39.44
8/14/2001	\$44.90	1,300,973	\$34.98	220,000	\$5.92	\$38.98
8/15/2001	\$44.87	1,300,973	\$35.00	220,000	\$5.92	\$38.95
8/16/2001	\$45.00	1,300,973	\$34.55	220,000	\$5.84	\$39.16
8/17/2001	\$44.44	1,300,973	\$34.66	220,000	\$5.86	\$38.58
8/20/2001	\$44.25	1,300,973	\$34.79	220,000	\$5.88	\$38.37
8/21/2001	\$44.16	1,300,973	\$34.49	220,000	\$5.83	\$38.33
8/22/2001	\$43.20	1,300,973	\$34.43	220,000	\$5.82	\$37.38
8/23/2001	\$42.40	1,300,973	\$34.60	220,000	\$5.85	\$36.55
8/24/2001	\$41.81	1,300,973	\$34.80	220,000	\$5.88	\$35.93
8/27/2001	\$41.83	1,300,973	\$34.65	220,000	\$5.86	\$35.97
8/28/2001	\$41.30	1,300,973	\$34.28	220,000	\$5.80	\$35.50
8/29/2001	\$40.51	1,300,973	\$34.11	220,000	\$5.77	\$34.74
8/30/2001	\$39.90	1,300,973	\$34.00	220,000	\$5.75	\$34.15
8/31/2001	\$39.60	1,301,517	\$34.11	220,000	\$5.77	\$33.83
9/4/2001	\$40.00	1,301,517	\$33.70	220,000	\$5.70	\$34.30
9/5/2001	\$40.80	1,301,517	\$33.80	220,000	\$5.71	\$35.09
9/6/2001	\$40.81	1,301,517	\$34.25	220,000	\$5.79	\$35.02
9/7/2001	\$40.27	1,301,517	\$33.39	220,000	\$5.64	\$34.63
9/10/2001	\$40.15	1,301,517	\$32.95	220,000	\$5.57	\$34.58
9/17/2001	\$39.50	1,301,517	\$31.26	220,000	\$5.28	\$34.22
9/18/2001	\$39.60	1,301,517	\$31.76	220,000	\$5.37	\$34.23
9/19/2001	\$40.00	1,301,517	\$32.00	220,000	\$5.41	\$34.59
9/20/2001	\$38.91	1,301,517	\$32.85	220,000	\$5.55	\$33.36
9/21/2001	\$38.35	1,301,517	\$33.20	220,000	\$5.61	\$32.74
9/24/2001	\$37.60	1,301,517	\$32.41	220,000	\$5.48	\$32.12

## Exhibit-6

### Pharmacia Pharmaceuticals Stock Price

(Pharmacia Stock Price Less Per Share Value of New Monsanto Holdings)

18 October 2000 through 18 October 2001

<b>Date</b>	<b>PHA Share Price</b>	<b>PHA Shares Outstanding</b>	<b>MON Share Price</b>	<b>MON Shares Owned by PHA</b>	<b>Value of MON per PHA Share</b>	<b>PHA Adjusted for MON</b>
9/25/2001	\$37.86	1,301,517	\$33.86	220,000	\$5.72	\$32.14
9/26/2001	\$38.74	1,301,517	\$33.81	220,000	\$5.72	\$33.02
9/27/2001	\$40.06	1,301,517	\$33.61	220,000	\$5.68	\$34.38
9/28/2001	\$40.56	1,301,517	\$33.73	220,000	\$5.70	\$34.86
10/1/2001	\$40.75	1,301,517	\$34.00	220,000	\$5.75	\$35.00
10/2/2001	\$41.31	1,301,517	\$34.00	220,000	\$5.75	\$35.56
10/3/2001	\$40.98	1,301,517	\$34.44	220,000	\$5.82	\$35.16
10/4/2001	\$40.05	1,301,517	\$34.75	220,000	\$5.87	\$34.18
10/5/2001	\$40.38	1,301,517	\$33.96	220,000	\$5.74	\$34.64
10/8/2001	\$39.94	1,301,517	\$33.64	220,000	\$5.69	\$34.25
10/9/2001	\$40.00	1,301,517	\$33.20	220,000	\$5.61	\$34.39
10/10/2001	\$40.41	1,301,517	\$34.95	220,000	\$5.91	\$34.50
10/11/2001	\$41.02	1,301,517	\$36.60	220,000	\$6.19	\$34.83
10/12/2001	\$41.03	1,301,517	\$36.75	220,000	\$6.21	\$34.82
10/15/2001	\$41.00	1,301,517	\$36.67	220,000	\$6.20	\$34.80
10/16/2001	\$41.20	1,301,517	\$36.98	220,000	\$6.25	\$34.95
10/17/2001	\$41.80	1,301,517	\$37.00	220,000	\$6.25	\$35.55
10/18/2001	\$41.90	1,301,517	\$36.34	220,000	\$6.14	\$35.76

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**Sources:** CRSP

Monsanto Company Form 10-Q, filed 30 November 2000.

Monsanto Company Form 10-K, filed 5 March 2002.

**Exhibit-7**

**CRSP Market Total Return Index (Market Index) and Peer Index Levels  
and Returns**

18 October 2000 through 18 October 2001

<b>Date</b>	<b>Market Index Level</b>	<b>Pharma Index Level</b>	<b>Market Index Logarithmic Return</b>	<b>Pharma Index Logarithmic Return</b>
10/18/2000	2,762.66	111.45		
10/19/2000	2,865.05	109.81	3.64%	-1.48%
10/20/2000	2,892.85	110.37	0.97%	0.50%
10/23/2000	2,893.15	112.56	0.01%	1.97%
10/24/2000	2,890.21	111.89	-0.10%	-0.60%
10/25/2000	2,810.93	113.84	-2.78%	1.73%
10/26/2000	2,812.50	112.64	0.06%	-1.05%
10/27/2000	2,836.76	111.46	0.86%	-1.06%
10/30/2000	2,855.80	112.78	0.67%	1.18%
10/31/2000	2,936.84	111.83	2.80%	-0.85%
11/1/2000	2,924.07	112.96	-0.44%	1.00%
11/2/2000	2,953.48	112.01	1.00%	-0.84%
11/3/2000	2,955.11	111.27	0.05%	-0.67%
11/6/2000	2,958.82	112.48	0.13%	1.08%
11/7/2000	2,955.94	111.31	-0.10%	-1.04%
11/8/2000	2,899.98	113.42	-1.91%	1.88%
11/9/2000	2,871.61	113.29	-0.98%	-0.12%
11/10/2000	2,795.74	113.99	-2.68%	0.62%
11/13/2000	2,758.42	109.37	-1.34%	-4.14%
11/14/2000	2,830.43	112.04	2.58%	2.42%
11/15/2000	2,846.02	112.48	0.55%	0.39%
11/16/2000	2,799.23	111.72	-1.66%	-0.68%
11/17/2000	2,786.59	113.02	-0.45%	1.16%
11/20/2000	2,719.98	113.11	-2.42%	0.07%
11/21/2000	2,720.82	114.89	0.03%	1.56%
11/22/2000	2,663.90	113.26	-2.11%	-1.43%
11/24/2000	2,720.16	112.44	2.09%	-0.73%
11/27/2000	2,730.10	116.17	0.36%	3.26%
11/28/2000	2,683.81	117.65	-1.71%	1.27%
11/29/2000	2,685.58	119.68	0.07%	1.71%
11/30/2000	2,633.89	118.12	-1.94%	-1.31%
12/1/2000	2,650.32	115.23	0.62%	-2.48%
12/4/2000	2,660.04	116.90	0.37%	1.44%
12/5/2000	2,780.65	116.34	4.43%	-0.48%
12/6/2000	2,734.85	112.98	-1.66%	-2.93%

**Exhibit-7**

**CRSP Market Total Return Index (Market Index) and Peer Index Levels  
and Returns**

18 October 2000 through 18 October 2001

<b>Date</b>	<b>Market Index Level</b>	<b>Pharma Index Level</b>	<b>Market Index Logarithmic Return</b>	<b>Pharma Index Logarithmic Return</b>
12/7/2000	2,718.68	114.05	-0.59%	0.94%
12/8/2000	2,796.12	114.88	2.81%	0.73%
12/11/2000	2,829.54	114.71	1.19%	-0.15%
12/12/2000	2,798.73	114.80	-1.09%	0.08%
12/13/2000	2,766.32	116.87	-1.16%	1.79%
12/14/2000	2,719.52	116.57	-1.71%	-0.26%
12/15/2000	2,671.32	115.93	-1.79%	-0.55%
12/18/2000	2,685.66	116.23	0.54%	0.26%
12/19/2000	2,643.05	117.54	-1.60%	1.12%
12/20/2000	2,550.03	118.82	-3.58%	1.09%
12/21/2000	2,563.86	118.11	0.54%	-0.60%
12/22/2000	2,641.22	116.54	2.97%	-1.34%
12/26/2000	2,655.70	118.84	0.55%	1.95%
12/27/2000	2,692.69	119.85	1.38%	0.85%
12/28/2000	2,718.06	122.23	0.94%	1.97%
12/29/2000	2,687.41	122.43	-1.13%	0.16%
1/2/2001	2,595.30	118.75	-3.49%	-3.04%
1/3/2001	2,732.67	113.07	5.16%	-4.90%
1/4/2001	2,700.38	108.86	-1.19%	-3.79%
1/5/2001	2,622.49	108.89	-2.93%	0.02%
1/8/2001	2,613.50	108.98	-0.34%	0.08%
1/9/2001	2,626.28	111.57	0.49%	2.35%
1/10/2001	2,662.61	109.91	1.37%	-1.50%
1/11/2001	2,702.45	107.05	1.49%	-2.64%
1/12/2001	2,692.95	109.17	-0.35%	1.96%
1/16/2001	2,709.73	111.25	0.62%	1.89%
1/17/2001	2,721.97	108.17	0.45%	-2.81%
1/18/2001	2,755.49	109.71	1.22%	1.41%
1/19/2001	2,744.18	108.21	-0.41%	-1.37%
1/22/2001	2,744.96	109.23	0.03%	0.94%
1/23/2001	2,788.40	109.38	1.57%	0.14%
1/24/2001	2,797.56	108.37	0.33%	-0.93%
1/25/2001	2,776.43	110.08	-0.76%	1.57%
1/26/2001	2,774.49	109.57	-0.07%	-0.47%
1/29/2001	2,799.38	108.20	0.89%	-1.26%

**Exhibit-7**

**CRSP Market Total Return Index (Market Index) and Peer Index Levels  
and Returns**

18 October 2000 through 18 October 2001

<b>Date</b>	<b>Market Index Level</b>	<b>Pharma Index Level</b>	<b>Market Index Logarithmic Return</b>	<b>Pharma Index Logarithmic Return</b>
1/30/2001	2,817.82	107.94	0.66%	-0.24%
1/31/2001	2,799.03	108.09	-0.67%	0.14%
2/1/2001	2,809.77	109.55	0.38%	1.35%
2/2/2001	2,757.46	110.68	-1.88%	1.03%
2/5/2001	2,763.15	109.79	0.21%	-0.81%
2/6/2001	2,764.56	109.14	0.05%	-0.60%
2/7/2001	2,740.28	110.43	-0.88%	1.18%
2/8/2001	2,722.45	110.90	-0.65%	0.42%
2/9/2001	2,683.62	110.99	-1.44%	0.08%
2/12/2001	2,711.47	112.13	1.03%	1.02%
2/13/2001	2,687.95	109.97	-0.87%	-1.95%
2/14/2001	2,687.68	108.03	-0.01%	-1.78%
2/15/2001	2,711.75	107.75	0.89%	-0.26%
2/16/2001	2,655.80	105.16	-2.08%	-2.43%
2/20/2001	2,605.83	106.07	-1.90%	0.85%
2/21/2001	2,557.98	106.49	-1.85%	0.40%
2/22/2001	2,546.42	104.85	-0.45%	-1.55%
2/23/2001	2,536.47	104.60	-0.39%	-0.24%
2/26/2001	2,585.16	106.46	1.90%	1.77%
2/27/2001	2,555.59	106.25	-1.15%	-0.21%
2/28/2001	2,520.48	107.72	-1.38%	1.38%
3/1/2001	2,521.38	106.99	0.04%	-0.68%
3/2/2001	2,508.91	107.18	-0.50%	0.17%
3/5/2001	2,522.57	106.75	0.54%	-0.40%
3/6/2001	2,551.51	104.78	1.14%	-1.87%
3/7/2001	2,566.98	102.47	0.60%	-2.23%
3/8/2001	2,563.74	104.15	-0.13%	1.63%
3/9/2001	2,501.31	104.99	-2.46%	0.80%
3/12/2001	2,395.50	102.44	-4.32%	-2.46%
3/13/2001	2,431.24	102.01	1.48%	-0.42%
3/14/2001	2,370.35	99.53	-2.54%	-2.45%
3/15/2001	2,378.24	98.99	0.33%	-0.54%
3/16/2001	2,328.72	96.54	-2.10%	-2.51%
3/19/2001	2,372.02	98.60	1.84%	2.11%
3/20/2001	2,317.30	97.04	-2.33%	-1.60%

**Exhibit-7**

**CRSP Market Total Return Index (Market Index) and Peer Index Levels  
and Returns**

18 October 2000 through 18 October 2001

<b>Date</b>	<b>Market Index Level</b>	<b>Pharma Index Level</b>	<b>Market Index Logarithmic Return</b>	<b>Pharma Index Logarithmic Return</b>
3/21/2001	2,274.00	93.47	-1.89%	-3.75%
3/22/2001	2,263.94	93.59	-0.44%	0.13%
3/23/2001	2,310.40	95.08	2.03%	1.58%
3/26/2001	2,336.14	95.98	1.11%	0.94%
3/27/2001	2,389.89	97.00	2.27%	1.06%
3/28/2001	2,327.65	99.10	-2.64%	2.14%
3/29/2001	2,315.14	99.37	-0.54%	0.27%
3/30/2001	2,343.18	99.28	1.20%	-0.09%
4/2/2001	2,306.75	97.25	-1.57%	-2.06%
4/3/2001	2,223.88	95.04	-3.66%	-2.30%
4/4/2001	2,216.55	96.42	-0.33%	1.44%
4/5/2001	2,318.33	98.72	4.49%	2.36%
4/6/2001	2,271.65	98.67	-2.03%	-0.06%
4/9/2001	2,292.59	99.85	0.92%	1.20%
4/10/2001	2,359.02	100.34	2.86%	0.49%
4/11/2001	2,357.12	97.75	-0.08%	-2.62%
4/12/2001	2,394.65	99.46	1.58%	1.74%
4/16/2001	2,382.79	100.34	-0.50%	0.88%
4/17/2001	2,407.74	102.92	1.04%	2.53%
4/18/2001	2,503.29	101.96	3.89%	-0.94%
4/19/2001	2,540.04	100.51	1.46%	-1.43%
4/20/2001	2,518.62	100.05	-0.85%	-0.46%
4/23/2001	2,476.48	100.10	-1.69%	0.05%
4/24/2001	2,449.65	98.41	-1.09%	-1.70%
4/25/2001	2,489.69	101.03	1.62%	2.62%
4/26/2001	2,502.15	102.48	0.50%	1.43%
4/27/2001	2,538.45	103.18	1.44%	0.69%
4/30/2001	2,540.37	103.61	0.08%	0.42%
5/1/2001	2,574.04	103.52	1.32%	-0.09%
5/2/2001	2,582.72	103.42	0.34%	-0.10%
5/3/2001	2,543.36	103.00	-1.54%	-0.40%
5/4/2001	2,578.86	103.94	1.39%	0.91%
5/7/2001	2,570.68	104.84	-0.32%	0.86%
5/8/2001	2,569.02	104.13	-0.06%	-0.68%
5/9/2001	2,557.81	104.53	-0.44%	0.38%

**Exhibit-7**

**CRSP Market Total Return Index (Market Index) and Peer Index Levels  
and Returns**

18 October 2000 through 18 October 2001

<b>Date</b>	<b>Market Index Level</b>	<b>Pharma Index Level</b>	<b>Market Index Logarithmic Return</b>	<b>Pharma Index Logarithmic Return</b>
5/10/2001	2,556.68	103.50	-0.04%	-0.99%
5/11/2001	2,537.53	103.68	-0.75%	0.17%
5/14/2001	2,539.97	104.00	0.10%	0.31%
5/15/2001	2,543.62	103.90	0.14%	-0.10%
5/16/2001	2,612.96	106.84	2.69%	2.79%
5/17/2001	2,628.22	108.41	0.58%	1.46%
5/18/2001	2,635.33	107.52	0.27%	-0.82%
5/21/2001	2,684.28	108.47	1.84%	0.87%
5/22/2001	2,679.81	107.79	-0.17%	-0.63%
5/23/2001	2,635.08	106.71	-1.68%	-1.01%
5/24/2001	2,645.96	106.58	0.41%	-0.12%
5/25/2001	2,619.73	106.57	-1.00%	-0.01%
5/29/2001	2,592.58	107.78	-1.04%	1.13%
5/30/2001	2,547.08	107.38	-1.77%	-0.37%
5/31/2001	2,566.52	107.65	0.76%	0.25%
6/1/2001	2,580.32	109.65	0.54%	1.84%
6/4/2001	2,593.43	110.87	0.51%	1.10%
6/5/2001	2,630.35	112.63	1.41%	1.57%
6/6/2001	2,605.51	111.70	-0.95%	-0.83%
6/7/2001	2,619.40	111.51	0.53%	-0.17%
6/8/2001	2,594.42	110.87	-0.96%	-0.57%
6/11/2001	2,569.50	109.59	-0.97%	-1.17%
6/12/2001	2,569.97	109.20	0.02%	-0.35%
6/13/2001	2,544.35	108.51	-1.00%	-0.64%
6/14/2001	2,495.49	108.47	-1.94%	-0.04%
6/15/2001	2,483.32	108.40	-0.49%	-0.06%
6/18/2001	2,466.78	108.31	-0.67%	-0.09%
6/19/2001	2,471.18	108.71	0.18%	0.37%
6/20/2001	2,495.33	109.54	0.97%	0.76%
6/21/2001	2,519.96	109.26	0.98%	-0.26%
6/22/2001	2,497.25	106.73	-0.91%	-2.34%
6/25/2001	2,485.07	105.63	-0.49%	-1.03%
6/26/2001	2,484.76	105.56	-0.01%	-0.07%
6/27/2001	2,479.63	104.02	-0.21%	-1.48%
6/28/2001	2,510.82	105.22	1.25%	1.15%

**Exhibit-7**

**CRSP Market Total Return Index (Market Index) and Peer Index Levels  
and Returns**

18 October 2000 through 18 October 2001

<b>Date</b>	<b>Market Index Level</b>	<b>Pharma Index Level</b>	<b>Market Index Logarithmic Return</b>	<b>Pharma Index Logarithmic Return</b>
6/29/2001	2,521.76	103.39	0.43%	-1.76%
7/2/2001	2,535.26	105.08	0.53%	1.62%
7/3/2001	2,530.81	105.20	-0.18%	0.11%
7/5/2001	2,500.13	104.55	-1.22%	-0.62%
7/6/2001	2,444.71	103.70	-2.24%	-0.81%
7/9/2001	2,458.65	105.91	0.57%	2.11%
7/10/2001	2,423.55	105.52	-1.44%	-0.38%
7/11/2001	2,418.04	105.82	-0.23%	0.29%
7/12/2001	2,475.03	104.55	2.33%	-1.21%
7/13/2001	2,488.32	105.69	0.54%	1.08%
7/16/2001	2,459.40	105.43	-1.17%	-0.25%
7/17/2001	2,485.55	107.22	1.06%	1.69%
7/18/2001	2,468.56	108.71	-0.69%	1.38%
7/19/2001	2,481.31	108.88	0.52%	0.15%
7/20/2001	2,474.06	109.48	-0.29%	0.55%
7/23/2001	2,437.79	108.04	-1.48%	-1.32%
7/24/2001	2,398.15	105.93	-1.64%	-1.97%
7/25/2001	2,430.99	107.11	1.36%	1.11%
7/26/2001	2,458.96	108.01	1.14%	0.83%
7/27/2001	2,467.04	108.17	0.33%	0.15%
7/30/2001	2,464.12	108.70	-0.12%	0.48%
7/31/2001	2,476.18	110.63	0.49%	1.76%
8/1/2001	2,488.64	109.82	0.50%	-0.73%
8/2/2001	2,496.69	109.58	0.32%	-0.21%
8/3/2001	2,485.12	109.28	-0.46%	-0.28%
8/6/2001	2,457.76	108.84	-1.11%	-0.40%
8/7/2001	2,463.25	109.42	0.22%	0.53%
8/8/2001	2,421.98	108.26	-1.69%	-1.07%
8/9/2001	2,421.59	107.96	-0.02%	-0.27%
8/10/2001	2,431.97	109.35	0.43%	1.28%
8/13/2001	2,437.69	110.06	0.23%	0.64%
8/14/2001	2,431.68	110.64	-0.25%	0.53%
8/15/2001	2,415.13	110.41	-0.68%	-0.21%
8/16/2001	2,419.73	109.21	0.19%	-1.09%
8/17/2001	2,381.16	108.14	-1.61%	-0.99%



**Exhibit-7**

**CRSP Market Total Return Index (Market Index) and Peer Index Levels  
and Returns**

18 October 2000 through 18 October 2001

<b>Date</b>	<b>Market Index Level</b>	<b>Pharma Index Level</b>	<b>Market Index Logarithmic Return</b>	<b>Pharma Index Logarithmic Return</b>
8/20/2001	2,397.40	110.00	0.68%	1.70%
8/21/2001	2,369.91	109.84	-1.15%	-0.14%
8/22/2001	2,387.49	111.02	0.74%	1.07%
8/23/2001	2,380.76	111.81	-0.28%	0.71%
8/24/2001	2,424.17	112.76	1.81%	0.85%
8/27/2001	2,415.12	112.08	-0.37%	-0.61%
8/28/2001	2,380.38	110.65	-1.45%	-1.28%
8/29/2001	2,357.54	109.56	-0.96%	-0.98%
8/30/2001	2,320.75	109.17	-1.57%	-0.36%
8/31/2001	2,330.26	107.67	0.41%	-1.39%
9/4/2001	2,326.39	110.65	-0.17%	2.73%
9/5/2001	2,318.84	112.58	-0.32%	1.73%
9/6/2001	2,270.76	110.90	-2.10%	-1.51%
9/7/2001	2,230.41	108.78	-1.79%	-1.92%
9/10/2001	2,238.24	109.85	0.35%	0.98%
9/17/2001	2,124.74	109.53	-5.20%	-0.29%
9/18/2001	2,107.11	107.05	-0.83%	-2.29%
9/19/2001	2,071.17	104.77	-1.72%	-2.15%
9/20/2001	2,007.72	102.65	-3.11%	-2.05%
9/21/2001	1,970.37	99.98	-1.88%	-2.63%
9/24/2001	2,044.80	101.05	3.71%	1.06%
9/25/2001	2,060.34	102.98	0.76%	1.90%
9/26/2001	2,047.91	105.17	-0.61%	2.11%
9/27/2001	2,069.83	107.91	1.06%	2.57%
9/28/2001	2,116.94	108.59	2.25%	0.62%
10/1/2001	2,107.55	109.92	-0.44%	1.22%
10/2/2001	2,131.93	110.73	1.15%	0.74%
10/3/2001	2,179.16	109.05	2.19%	-1.53%
10/4/2001	2,178.59	108.73	-0.03%	-0.30%
10/5/2001	2,179.50	110.07	0.04%	1.23%
10/8/2001	2,162.73	109.76	-0.77%	-0.28%
10/9/2001	2,152.31	109.20	-0.48%	-0.52%
10/10/2001	2,202.16	110.86	2.29%	1.51%
10/11/2001	2,240.42	109.68	1.72%	-1.07%
10/12/2001	2,228.37	109.85	-0.54%	0.15%

**Exhibit-7**

**CRSP Market Total Return Index (Market Index) and Peer Index Levels  
and Returns**

18 October 2000 through 18 October 2001

<b>Date</b>	<b>Market Index Level</b>	<b>Pharma Index Level</b>	<b>Market Index Logarithmic Return</b>	<b>Pharma Index Logarithmic Return</b>
10/15/2001	2,226.84	110.74	-0.07%	0.81%
10/16/2001	2,244.31	111.59	0.78%	0.77%
10/17/2001	2,200.81	111.00	-1.96%	-0.54%
10/18/2001	2,185.49	111.00	-0.70%	0.01%

---

**Sources:** CRSP

Dow Jones

### Exhibit-8

#### Pharmacia Pharmaceuticals Stock Regression Results

Estimation Period: 19 October 2000 through 18 October 2001

Regression Statistics	
Multiple R	0.605
R Square	0.366
Adjusted R Square	0.345
Standard Error	1.93%
Observations	248
F-Statistic	17.24
F-Statistic Significance Level	~0.00%

	Coefficients	Standard Error	<i>t</i> -statistic
Intercept	-0.10%	0.12%	-0.812
Market Index	0.012	0.083	0.141
Pharmaceutical Index	0.953	0.090	10.570
6 February 2001	-0.74%	1.93%	-0.381
7 February 2001	-4.17%	1.93%	-2.155
8 February 2001	-6.91%	1.93%	-3.578
6 August 2001	0.71%	1.93%	0.368
7 August 2001	3.09%	1.93%	1.599
8 August 2001	-1.07%	1.94%	-0.551

**Exhibit-9**

**Pharmacia Pharmaceuticals Stock Event Study Results**

<b>Date</b>	<b>PHA Pharma Stock Closing Price</b>	<b>PHA Pharma Stock Closing Price on Previous Trading Day</b>	<b>PHA Pharma Stock Logarithmic Return</b>	<b>Market Index Logarithmic Return</b>	<b>Pharma Index Logarithmic Return</b>	<b>PHA Pharma Stock Explained Return</b>	<b>PHA Pharma Stock Residual Return</b>	<b>t -statistic</b>	<b>p-value</b>	<b>Statistically Significant</b>	<b>Dollar Residual Return</b>
6 February 2001	\$52.41	\$53.16	-1.42%	0.05%	-0.62%	-0.69%	-0.74%	-0.38	0.7027	No	(\$0.39)
7 February 2001	\$50.78	\$52.41	-3.15%	-0.88%	1.19%	1.02%	-4.17%	-2.16	0.0314	Yes	(\$2.14)
8 February 2001	\$47.54	\$50.78	-6.61%	-0.65%	0.43%	0.30%	-6.91%	-3.59	0.0004	Yes	(\$3.39)
<b>3-Day</b>			<b>-11.18%</b>	<b>-1.48%</b>	<b>1.00%</b>	<b>0.64%</b>	<b>-11.81%</b>	<b>-3.54</b>	<b>0.0005</b>	<b>Yes</b>	<b>(\$5.92)</b>
6 August 2001	\$37.83	\$37.74	0.22%	-1.11%	-0.40%	-0.49%	0.71%	0.37	0.7122	No	\$0.27
7 August 2001	\$39.17	\$37.83	3.49%	0.22%	0.53%	0.40%	3.09%	1.60	0.1102	No	\$1.19
8 August 2001	\$38.32	\$39.17	-2.20%	-1.69%	-1.06%	-1.13%	-1.07%	-0.55	0.5802	No	(\$0.42)
<b>3-Day</b>			<b>1.51%</b>	<b>-2.57%</b>	<b>-0.94%</b>	<b>-1.22%</b>	<b>2.73%</b>	<b>0.82</b>	<b>0.4135</b>	<b>No</b>	<b>\$1.04</b>

## Exhibit-10

### S&P Chemicals Index Levels and Returns

18 October 2000 through 18 October 2001

Date	Chemicals Index Level	Chemicals Index Logarithmic Return
10/18/2000	155.33	
10/19/2000	152.07	-2.12%
10/20/2000	152.39	0.21%
10/23/2000	152.69	0.20%
10/24/2000	161.25	5.45%
10/25/2000	159.00	-1.40%
10/26/2000	160.09	0.68%
10/27/2000	162.67	1.60%
10/30/2000	174.10	6.79%
10/31/2000	176.24	1.22%
11/1/2000	172.91	-1.91%
11/2/2000	172.78	-0.07%
11/3/2000	173.74	0.55%
11/6/2000	172.48	-0.73%
11/7/2000	174.40	1.11%
11/8/2000	177.82	1.94%
11/9/2000	174.80	-1.71%
11/10/2000	171.08	-2.15%
11/13/2000	171.86	0.45%
11/14/2000	173.28	0.83%
11/15/2000	175.82	1.45%
11/16/2000	169.62	-3.59%
11/17/2000	172.01	1.40%
11/20/2000	168.54	-2.04%
11/21/2000	167.61	-0.55%
11/22/2000	166.69	-0.56%
11/24/2000	167.75	0.64%
11/27/2000	165.73	-1.21%
11/28/2000	164.40	-0.81%
11/29/2000	169.78	3.22%
11/30/2000	169.92	0.09%
12/1/2000	175.31	3.12%
12/4/2000	186.10	5.97%
12/5/2000	188.46	1.26%
12/6/2000	182.10	-3.43%
12/7/2000	176.73	-2.99%

## Exhibit-10

### S&P Chemicals Index Levels and Returns

18 October 2000 through 18 October 2001

Date	Chemicals Index Level	Chemicals Index Logarithmic Return
12/8/2000	178.91	1.22%
12/11/2000	175.84	-1.73%
12/12/2000	175.73	-0.07%
12/13/2000	176.14	0.24%
12/14/2000	177.69	0.87%
12/15/2000	172.86	-2.75%
12/18/2000	178.94	3.45%
12/19/2000	183.61	2.58%
12/20/2000	179.69	-2.16%
12/21/2000	187.37	4.18%
12/22/2000	194.62	3.80%
12/26/2000	195.84	0.63%
12/27/2000	200.04	2.12%
12/28/2000	201.44	0.70%
12/29/2000	197.21	-2.12%
1/2/2001	192.84	-2.24%
1/3/2001	194.29	0.75%
1/4/2001	200.35	3.08%
1/5/2001	194.24	-3.10%
1/8/2001	195.87	0.84%
1/9/2001	187.86	-4.18%
1/10/2001	187.82	-0.02%
1/11/2001	182.08	-3.10%
1/12/2001	178.59	-1.94%
1/16/2001	183.41	2.67%
1/17/2001	181.82	-0.87%
1/18/2001	180.69	-0.62%
1/19/2001	175.99	-2.64%
1/22/2001	174.79	-0.68%
1/23/2001	175.74	0.54%
1/24/2001	175.89	0.09%
1/25/2001	177.73	1.04%
1/26/2001	175.01	-1.54%
1/29/2001	175.44	0.25%
1/30/2001	183.06	4.25%
1/31/2001	185.43	1.29%

## Exhibit-10

### S&P Chemicals Index Levels and Returns

18 October 2000 through 18 October 2001

Date	Chemicals Index Level	Chemicals Index Logarithmic Return
2/1/2001	185.45	0.01%
2/2/2001	183.59	-1.01%
2/5/2001	186.55	1.60%
2/6/2001	185.07	-0.80%
2/7/2001	186.09	0.55%
2/8/2001	183.17	-1.58%
2/9/2001	182.03	-0.62%
2/12/2001	182.19	0.08%
2/13/2001	184.16	1.08%
2/14/2001	183.28	-0.48%
2/15/2001	188.61	2.87%
2/16/2001	184.54	-2.18%
2/20/2001	183.73	-0.44%
2/21/2001	181.83	-1.04%
2/22/2001	182.45	0.34%
2/23/2001	177.94	-2.50%
2/26/2001	187.21	5.08%
2/27/2001	187.81	0.32%
2/28/2001	188.63	0.44%
3/1/2001	189.23	0.31%
3/2/2001	192.68	1.81%
3/5/2001	196.05	1.73%
3/6/2001	196.10	0.03%
3/7/2001	202.36	3.14%
3/8/2001	204.98	1.29%
3/9/2001	202.73	-1.10%
3/12/2001	195.73	-3.51%
3/13/2001	192.41	-1.71%
3/14/2001	186.70	-3.01%
3/15/2001	183.65	-1.65%
3/16/2001	182.80	-0.46%
3/19/2001	188.17	2.90%
3/20/2001	185.76	-1.29%
3/21/2001	182.06	-2.01%
3/22/2001	175.47	-3.69%
3/23/2001	177.30	1.04%

## Exhibit-10

### S&P Chemicals Index Levels and Returns

18 October 2000 through 18 October 2001

Date	Chemicals Index Level	Chemicals Index Logarithmic Return
3/26/2001	180.67	1.89%
3/27/2001	183.11	1.34%
3/28/2001	181.49	-0.89%
3/29/2001	180.56	-0.51%
3/30/2001	179.17	-0.77%
4/2/2001	181.44	1.26%
4/3/2001	177.32	-2.29%
4/4/2001	182.27	2.75%
4/5/2001	189.24	3.75%
4/6/2001	185.84	-1.81%
4/9/2001	188.29	1.31%
4/10/2001	196.03	4.03%
4/11/2001	192.40	-1.87%
4/12/2001	193.72	0.69%
4/16/2001	194.08	0.18%
4/17/2001	193.98	-0.05%
4/18/2001	201.09	3.60%
4/19/2001	197.92	-1.59%
4/20/2001	194.81	-1.59%
4/23/2001	192.32	-1.28%
4/24/2001	193.84	0.79%
4/25/2001	192.53	-0.68%
4/26/2001	197.73	2.66%
4/27/2001	198.10	0.19%
4/30/2001	194.32	-1.93%
5/1/2001	195.27	0.49%
5/2/2001	198.11	1.45%
5/3/2001	197.37	-0.37%
5/4/2001	201.75	2.19%
5/7/2001	199.62	-1.06%
5/8/2001	201.87	1.12%
5/9/2001	202.53	0.33%
5/10/2001	206.25	1.82%
5/11/2001	203.87	-1.16%
5/14/2001	206.19	1.13%
5/15/2001	206.55	0.17%



## Exhibit-10

### S&P Chemicals Index Levels and Returns

18 October 2000 through 18 October 2001

Date	Chemicals Index Level	Chemicals Index Logarithmic Return
5/16/2001	215.97	4.46%
5/17/2001	217.77	0.83%
5/18/2001	214.76	-1.39%
5/21/2001	215.52	0.35%
5/22/2001	213.65	-0.87%
5/23/2001	208.63	-2.38%
5/24/2001	202.50	-2.98%
5/25/2001	202.24	-0.13%
5/29/2001	204.86	1.29%
5/30/2001	201.10	-1.85%
5/31/2001	203.50	1.19%
6/1/2001	202.27	-0.61%
6/4/2001	205.05	1.36%
6/5/2001	205.34	0.14%
6/6/2001	204.70	-0.31%
6/7/2001	206.41	0.83%
6/8/2001	205.18	-0.59%
6/11/2001	203.86	-0.65%
6/12/2001	202.93	-0.46%
6/13/2001	203.44	0.25%
6/14/2001	198.62	-2.40%
6/15/2001	197.16	-0.74%
6/18/2001	197.79	0.32%
6/19/2001	200.10	1.16%
6/20/2001	201.78	0.84%
6/21/2001	200.57	-0.60%
6/22/2001	195.55	-2.54%
6/25/2001	193.35	-1.13%
6/26/2001	195.42	1.06%
6/27/2001	197.02	0.82%
6/28/2001	197.44	0.22%
6/29/2001	198.71	0.64%
7/2/2001	200.99	1.14%
7/3/2001	198.54	-1.22%
7/5/2001	199.00	0.23%
7/6/2001	195.75	-1.65%

## Exhibit-10

### S&P Chemicals Index Levels and Returns

18 October 2000 through 18 October 2001

<b>Date</b>	<b>Chemicals Index Level</b>	<b>Chemicals Index Logarithmic Return</b>
7/9/2001	197.64	0.96%
7/10/2001	196.29	-0.69%
7/11/2001	195.04	-0.64%
7/12/2001	197.44	1.22%
7/13/2001	196.70	-0.38%
7/16/2001	194.82	-0.96%
7/17/2001	194.62	-0.10%
7/18/2001	197.98	1.72%
7/19/2001	200.82	1.42%
7/20/2001	198.49	-1.17%
7/23/2001	193.69	-2.45%
7/24/2001	188.43	-2.75%
7/25/2001	191.82	1.78%
7/26/2001	192.62	0.41%
7/27/2001	189.75	-1.50%
7/30/2001	189.18	-0.30%
7/31/2001	193.76	2.39%
8/1/2001	191.83	-1.00%
8/2/2001	194.49	1.38%
8/3/2001	194.47	-0.01%
8/6/2001	193.80	-0.34%
8/7/2001	192.76	-0.54%
8/8/2001	189.01	-1.96%
8/9/2001	188.50	-0.27%
8/10/2001	191.58	1.62%
8/13/2001	191.59	0.00%
8/14/2001	191.48	-0.05%
8/15/2001	191.35	-0.07%
8/16/2001	188.64	-1.43%
8/17/2001	188.20	-0.24%
8/20/2001	187.65	-0.29%
8/21/2001	189.02	0.73%
8/22/2001	189.56	0.28%
8/23/2001	189.92	0.19%
8/24/2001	194.74	2.51%
8/27/2001	194.99	0.13%

## Exhibit-10

### S&P Chemicals Index Levels and Returns

18 October 2000 through 18 October 2001

Date	Chemicals Index Level	Chemicals Index Logarithmic Return
8/28/2001	192.08	-1.50%
8/29/2001	190.40	-0.88%
8/30/2001	188.38	-1.07%
8/31/2001	190.53	1.14%
9/4/2001	192.68	1.12%
9/5/2001	191.95	-0.38%
9/6/2001	189.63	-1.21%
9/7/2001	184.59	-2.70%
9/10/2001	182.14	-1.34%
9/17/2001	164.43	-10.23%
9/18/2001	166.10	1.01%
9/19/2001	163.21	-1.76%
9/20/2001	157.43	-3.61%
9/21/2001	154.51	-1.87%
9/24/2001	165.35	6.78%
9/25/2001	165.93	0.35%
9/26/2001	165.13	-0.49%
9/27/2001	167.95	1.70%
9/28/2001	174.24	3.68%
10/1/2001	173.41	-0.48%
10/2/2001	173.99	0.33%
10/3/2001	175.76	1.01%
10/4/2001	174.76	-0.57%
10/5/2001	175.90	0.65%
10/8/2001	173.30	-1.49%
10/9/2001	174.72	0.82%
10/10/2001	179.97	2.96%
10/11/2001	187.83	4.28%
10/12/2001	185.64	-1.17%
10/15/2001	183.95	-0.92%
10/16/2001	185.36	0.76%
10/17/2001	182.31	-1.66%
10/18/2001	182.37	0.03%

---

**Source:** Capital IQ

## Exhibit-11

### Pharmacia Stock Regression Results

Estimation Period: 19 October 2000 through 18 October 2001

Regression Statistics	
Multiple R	0.612
R Square	0.375
Adjusted R Square	0.351
Standard Error	1.71%
Observations	248
F-Statistic	15.85
F-Statistic Significance Level	~0.00%

	Coefficients	Standard Error	t- statistic
Intercept	-0.07%	0.11%	-0.659
Market Index	0.015	0.088	0.172
Pharmaceutical Index	0.849	0.081	10.483
Chemicals Index	0.053	0.067	0.790
6 February 2001	-0.45%	1.72%	-0.261
7 February 2001	-3.62%	1.72%	-2.104
8 February 2001	-5.94%	1.72%	-3.452
6 August 2001	0.44%	1.72%	0.259
7 August 2001	2.12%	1.72%	1.234
8 August 2001	-0.64%	1.72%	-0.371

**Exhibit-12**

**Pharmacia Stock Event Study Results**

Date	PHA Closing Stock Price	PHA Closing Stock Price on Previous Trading Day	PHA Logarithmic Return	Market Index Logarithmic Return	Pharma Index Logarithmic Return	Chemicals Index Logarithmic Return	PHA Explained Return	PHA Residual Return	t-statistic	p-value	Statistically Significant	Dollar Residual Return
6 February 2001	\$57.65	\$58.28	-1.09%	0.05%	-0.62%	-0.80%	-0.64%	-0.45%	-0.26	0.7933	No	(\$0.26)
7 February 2001	\$56.13	\$57.65	-2.67%	-0.88%	1.19%	0.55%	0.95%	-3.62%	-2.11	0.0355	Yes	(\$2.05)
8 February 2001	\$53.00	\$56.13	-5.74%	-0.65%	0.43%	-1.58%	0.20%	-5.94%	-3.47	0.0006	Yes	(\$3.24)
<b>3-Day</b>			<b>-9.50%</b>	<b>-1.48%</b>	<b>1.00%</b>	<b>-1.83%</b>	<b>0.51%</b>	<b>-10.01%</b>	<b>-3.37</b>	<b>0.0009</b>	<b>Yes</b>	<b>(\$5.55)</b>
6 August 2001	\$44.00	\$44.00	0.00%	-1.11%	-0.40%	-0.34%	-0.44%	0.44%	0.26	0.7954	No	\$0.20
7 August 2001	\$45.10	\$44.00	2.47%	0.22%	0.53%	-0.54%	0.35%	2.12%	1.24	0.2170	No	\$0.94
8 August 2001	\$44.32	\$45.10	-1.74%	-1.69%	-1.06%	-1.96%	-1.11%	-0.64%	-0.37	0.7095	No	(\$0.29)
<b>3-Day</b>			<b>0.72%</b>	<b>-2.57%</b>	<b>-0.94%</b>	<b>-2.85%</b>	<b>-1.20%</b>	<b>1.93%</b>	<b>0.65</b>	<b>0.5168</b>	<b>No</b>	<b>\$0.85</b>

## **Exhibit-13**

### **Inflation Ribbon**

<b>Dates</b>	<b>Inflation</b>
17 April 2000 - 6 February 2001	\$5.92
6 February 2001	\$5.53
7 February 2001	\$3.39
8 February 2001* - 2 November 2001	\$0.00

---

**Note:** [\*] As of Market Close

## **Exhibit-14**

### **New York Stock Exchange Specialist Participation Rates**

April 2000 through November 2001

<b>Date</b>	<b>NYSE Specialist Participation Rate</b>
April 2000	14.8%
May 2000	14.3%
June 2000	13.4%
July 2000	14.0%
August 2000	13.8%
September 2000	13.2%
October 2000	13.5%
November 2000	13.5%
December 2000	13.2%
January 2001	13.3%
February 2001	15.5%
March 2001	15.4%
April 2001	15.3%
May 2001	15.2%
June 2001	15.0%
July 2001	15.4%
August 2001	15.9%
September 2001	13.9%
October 2001	15.8%
November 2001	15.4%

---

**Source:** NYSE Technologies Market Data

[<http://www.nyxdata.com/Data-Products/Facts-and-Figures>]

## **Exhibit-15**

### **Pharmacia Short Interest**

April 2000 through November 2001

<b>Date</b>	<b>Short Interest</b>
4/14/2000	17,960,007
5/15/2000	11,920,988
6/15/2000	10,693,712
7/14/2000	11,690,459
8/15/2000	11,481,697
9/15/2000	12,248,375
10/13/2000	11,723,874
11/15/2000	13,239,407
12/15/2000	13,266,336
1/12/2001	13,236,718
2/15/2001	11,469,643
3/15/2001	12,362,266
4/12/2001	14,117,564
5/15/2001	10,245,493
6/15/2001	11,098,435
7/13/2001	14,029,817
8/15/2001	16,481,198
9/10/2001	14,219,380
10/15/2001	11,198,438
11/15/2001	15,933,075

---

**Source:** Bloomberg



**Exhibit-16**

**Shares Held by Institutions During the Class Period**

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
1838 Investment Advisors	2,912,532.9	394,207.1	161,549.3	110,455.0	69,344.3	48,775.0	42,672.1	40,917.1
3Bridge Capital LLC	-	-	-	-	-	-	223,884.3	229,859.3
3I Investments PLC	-	-	-	-	-	-	-	45,635.7
A I M Management Group Inc.	2,690,400.0	2,749,970.0	4,074,270.0	7,140,070.0	9,083,235.7	6,447,940.0	4,517,654.3	2,851,284.3
Aberdeen Asset Management PLC	-	-	283,700.0	374,900.0	338,300.0	33,300.0	-	325,400.0
ABN AMRO Asset Management Holdings, Inc.	-	-	-	-	37,850.7	26,779.3	20,179.3	10,279.3
Abner, Herrman & Brock, Inc.	54,082.9	88,750.0	106,964.3	104,507.9	104,780.7	102,045.7	103,470.0	119,564.3
Acadia Trust NA	10,300.0	10,657.1	10,569.3	10,469.3	9,394.3	10,644.3	10,644.3	11,019.3
Acadian Asset Management	-	-	2,200.0	-	-	-	-	-
Adage Capital Partners Gp, L.L.C.	-	-	-	-	-	-	-	940,310.0
Adams Express Company	310,000.0	368,900.0	368,900.0	368,900.0	368,900.0	368,900.0	368,900.0	368,900.0
Adams, Harkness & Hill, Inc.	-	2,600.0	2,022.1	-	-	-	-	-
Advanced Investment Management LP	10,870.0	10,869.3	34,647.1	34,647.1	15,302.9	5,484.3	5,484.3	-
Advantus Capital Management	50,002.1	541,642.9	756,850.7	871,152.1	983,410.7	234,430.0	334,067.9	353,375.0
Advest Bank And Trust Company	-	-	14,079.3	-	14,119.3	15,049.3	14,034.3	15,717.9
Advest Group, Inc. (The)	17,239.3	15,687.1	14,837.1	15,582.1	15,932.1	15,155.0	13,450.7	20,547.1
Advisory Research, Inc.	3,935.0	-	-	-	-	27,210.0	27,520.7	27,317.9
Aeltus Investment Management Inc.	753,219.3	1,857,482.9	3,521,385.7	3,937,937.1	900,627.1	918,575.0	2,496,912.1	1,302,440.0
Agf Investments Inc.	-	-	-	-	-	79,300.0	81,300.0	3,500.0
Albion Financial Group	-	-	-	100.0	100.0	100.0	100.0	100.0
Alger (Fred) Management Inc	-	-	-	970,300.0	881,860.0	-	-	-
Alleghany Corp	18,167.9	19,694.3	25,097.9	33,950.7	-	-	-	-
Allegiant Investment Counselors	-	-	-	116,312.1	116,200.7	103,800.7	101,664.3	114,564.3
Allen Holding Inc.	-	190,700.0	353,000.0	353,000.0	-	-	-	-
Allianz Dresdner Asset Management of America, Inc.	27,068,259.3	19,105,347.1	4,155,455.7	3,776,135.0	3,910,395.0	4,035,872.1	1,880,427.1	1,369,002.1
Allianz of America	-	-	-	-	-	1,306,000.0	1,252,700.0	1,284,600.0
Allied Irish Banks, P.L.C.	291,525.0	284,795.7	272,207.1	270,910.7	201,367.1	215,930.7	212,562.9	234,577.9
Allstate Insurance Co	163,000.0	-	-	195,152.9	243,752.9	110,930.7	445,830.7	649,630.7
Allstate Life Insurance Co	11,700.0	-	-	14,615.7	14,715.7	7,689.3	15,589.3	-
Allstate Pension Plan	25,800.0	-	-	36,925.0	26,825.0	-	57,600.0	92,800.0
Allstate Retirement Plan	74,400.0	-	-	83,057.1	60,857.1	-	137,200.0	221,200.0
Altrinsic Global Advisors, LLC	-	-	-	-	-	-	-	63,500.0
Amalgamated Bank of New York	426,522.9	433,142.9	438,842.9	454,942.9	441,642.9	432,042.9	428,242.9	446,242.9
Amarillo National Bank	-	-	-	-	-	21,159.3	31,842.9	43,565.7
Amcore Bank, N.A.	19,860.0	26,010.0	25,897.9	25,697.9	15,997.9	15,997.9	15,812.9	14,959.3
American Century Investment Management Inc.	249,900.0	215,600.0	1,447,900.0	11,401,100.0	12,718,000.0	12,551,267.9	10,175,097.1	6,185,829.3
American Express Financial Corp	4,450,987.9	6,641,295.7	10,104,262.9	6,186,967.9	2,363,839.3	4,065,825.0	5,496,302.1	4,831,980.0
American Fund Advisors, Inc	16,189.3	-	-	-	-	-	-	-

**Exhibit-16**

**Shares Held by Institutions During the Class Period**

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
American International Group, Inc	792,900.0	919,509.3	2,686,380.0	992,087.1	1,406,627.9	1,162,897.9	1,085,277.9	1,867,979.3
American National Bank & Trust Company	5,000.0	9,395.0	10,227.9	10,227.9	10,227.9	10,227.9	5,000.0	5,000.0
American Re Asset Management	186,105.7	-	-	-	-	-	-	-
Ameriserv Trust & Financial Services	23,225.0	22,225.0	-	-	-	-	-	-
Ameritas Life Insurance Corporation	2,162.9	43,884.3	35,250.0	-	-	-	-	-
AMI Investment Management, Inc.	-	-	-	-	-	-	-	-
Amsouth Bancorporation	889,449.3	908,052.1	904,472.1	734,957.9	745,015.7	424,935.0	935,574.3	898,939.3
Analytic Asset Management, Inc.	-	-	-	-	-	-	500.0	-
Analytic Investors, LLC	15,057.9	-	-	-	10,815.7	19,157.9	575,254.3	541,495.0
Anchor Capital Advisors, Inc.	165,317.1	96,385.7	92,417.1	95,530.7	99,072.1	100,760.0	100,282.9	116,979.3
Appleton Partners, Inc./Ma	19,727.1	22,834.3	14,427.1	21,002.9	21,002.9	19,002.9	8,775.7	8,775.7
Arcadia Investment Management Corporation	45,564.3	47,789.3	62,560.7	61,882.9	59,635.7	59,584.3	60,730.0	59,057.1
Arden Group (The)	-	6,970.0	7,370.0	7,370.0	7,165.0	6,570.0	6,570.0	17,855.0
Area Trust Company	-	-	-	-	-	4,637.9	-	4,637.9
Argent Capital Management	-	-	15,737.1	-	14,112.1	13,660.0	13,905.7	-
Argus Management LLC	-	-	-	-	-	-	-	200,000.0
Ark Asset Management Company, Inc.	396,900.0	-	28,132.9	99,792.1	161,492.1	163,492.1	117,192.1	1,641,359.3
Arnhold & S. Bleichroeder, Inc.	141,310.0	8,810.0	8,810.0	5,310.0	5,310.0	5,310.0	10,310.0	10,310.0
Arrowstreet Capital, Limited Partnership	-	-	-	-	-	-	-	9,900.0
Artisan Partners Limited Partnership	683,200.0	1,789,589.3	2,199,689.3	2,795,889.3	3,910,589.3	-	-	-
Ashfield & Company, Inc.	10,490.0	14,100.7	19,225.7	19,100.7	38,325.7	20,685.7	20,729.3	18,132.9
Asset Advisors Corporation	1,780.0	2,582.1	2,455.7	3,035.7	3,035.7	3,035.7	3,035.7	3,035.7
Asset Management Inc/Md	-	-	-	4,584.3	5,834.3	5,834.3	5,334.3	5,649.3
Asset Management Partners, Inc.	19,000.0	13,000.0	12,000.0	-	-	-	-	-
Associated Banc-Corp	19,262.9	19,662.9	16,870.7	22,115.0	24,375.0	25,005.7	28,255.7	29,772.9
Atalanta/Sosnoff Capital LLC	-	-	-	-	30,000.0	-	-	-
Atlanta Capital Management Company LLC	-	-	-	-	-	-	-	2,175.0
Atlantic Trust Company National Association	74,789.3	50,772.1	45,470.7	39,150.0	34,494.3	863,805.7	894,742.9	197,865.0
Avery Capital Management, L.L.C.	-	18,500.0	-	18,500.0	18,500.0	18,500.0	18,500.0	18,500.0
Aviva PLC	-	-	-	-	887,980.7	1,616,450.7	1,676,085.0	1,471,022.9
AXA	13,599,129.3	17,961,387.1	17,646,157.9	43,340,449.3	92,891,760.7	107,105,530.7	65,344,522.9	38,632,709.3
Axe-Houghton Associates, Inc.	142,535.0	139,535.0	137,035.0	137,035.0	137,035.0	137,035.0	137,035.0	164,635.0
Ayco Company, LP(The)	25,697.1	31,812.1	30,102.9	20,742.9	21,330.0	20,712.9	20,437.9	20,532.9
Babson Capital Management LLC	3,363,800.7	3,075,177.9	2,955,710.7	2,488,040.7	440,270.7	386,042.9	389,059.3	361,864.3
Babson-United Investment Advisors, Inc.	-	-	-	-	4,144.3	-	-	-
Back Bay Advisors, L.P.	19,300.0	14,337.1	14,337.1	14,337.1	14,337.1	-	-	-
Bahl & Gaynor, Inc.	8,810.0	14,977.9	-	10,377.9	9,377.9	8,377.9	8,377.9	6,877.9
Baird (Robert W.) & Company, Inc.	16,630.0	17,070.0	15,037.1	10,504.3	7,714.3	7,517.1	4,937.1	-

**Exhibit-16**

**Shares Held by Institutions During the Class Period**

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
Baker Investment Group, LLC	-	-	-	-	5,000.0	-	-	-
Baldwin Brothers, Inc.	6,255.0	8,900.0	5,140.0	5,640.0	5,640.0	5,640.0	5,492.1	5,385.0
Bancorpsouth, Inc.	23,740.0	22,040.0	22,240.0	22,240.0	20,090.0	-	-	-
Bank Julius Baer & Company, New York Branch	4,005.7	4,965.7	4,965.7	4,965.7	4,965.7	10,665.7	7,080.7	5,580.7
Bank of America Corporation	5,856,169.3	673,575.0	708,090.0	895,220.7	971,700.0	9,722,555.7	5,846,795.7	6,359,430.7
Bank of Hawaii	32,450.0	32,380.7	31,655.7	30,365.7	27,855.7	28,205.7	27,892.9	26,277.1
Bank of New York Co	1,680,187.9	1,657,267.9	1,294,364.3	1,253,582.1	1,221,990.0	1,158,385.0	1,152,747.1	1,170,352.1
Bank of New York Trust Company of Florida, N.A.	7,719.3	7,250.0	6,650.0	6,550.0	7,000.0	6,500.0	6,500.0	5,500.0
Bank of Oklahoma, N.A.	13,435.0	-	-	-	-	-	-	-
Bank of The West	9,150.0	10,985.7	10,985.7	10,772.1	10,172.1	10,172.1	10,472.1	10,472.1
Bank One Corporation	3,428,535.7	760,334.3	5,094,034.3	2,643,282.1	2,522,692.9	2,646,592.1	3,295,267.9	3,597,092.1
Bankers Trust Company (Iowa)	-	-	-	3,935.0	-	-	-	-
Bankmont Financial Corp.	548,905.0	-	555,362.1	585,492.9	667,492.9	663,487.9	1,052,347.1	698,942.1
Banknorth Investment Management Group	12,795.0	74,837.1	71,052.1	69,014.3	65,444.3	62,250.0	59,737.9	50,717.1
Barclays Bank PLC	31,923,520.0	37,882,657.9	37,859,845.7	38,138,292.1	38,805,485.0	40,721,334.3	41,502,545.7	45,921,295.7
Baring Asset Management, Inc.	-	-	-	-	-	-	5,690.0	13,790.0
Barrett Associates, Inc.	7,445.7	24,135.0	23,842.9	23,842.9	23,900.7	-	-	-
Barrow, Hanley Mewhinney & Strauss, Inc.	1,476,067.9	1,354,732.9	971,715.7	549,115.7	547,274.3	548,475.0	553,575.0	546,765.0
BBT Fund, LP	-	-	-	-	-	57,300.0	55,600.0	41,000.0
Beach Investment Counsel, Inc./PA	19,000.0	19,000.0	-	-	-	-	-	-
Beacon Fiduciary Advisors	4,370.0	4,870.0	6,870.0	7,970.0	8,315.0	8,315.0	11,552.1	13,552.1
Beacon Investment Company	-	-	-	4,795.0	4,795.0	4,795.0	-	-
Beacon Trust Company	23,017.1	22,667.1	22,332.9	22,417.1	22,242.1	20,900.0	20,900.0	20,900.0
Bear Stearns & Company	1,006,862.1	1,262,992.1	1,280,075.7	1,392,060.7	1,284,455.0	1,397,217.1	1,366,280.0	1,264,375.0
Bear Stearns Asset Management, Inc.	-	654.3	654.3	354.3	-	-	-	-
Beck, Mack & Oliver	7,950.0	3,950.0	-	-	-	-	-	-
Becker Capital Management Inc.	12,000.0	12,000.0	12,000.0	10,000.0	8,642.9	8,142.9	8,142.9	8,392.9
Beese, Fulmer & Pincoe, Inc.	50,802.1	54,874.3	54,949.3	54,422.9	54,672.9	47,195.0	48,112.1	48,837.1
Bel Air Investment Advisors LLC	-	5,015.7	3,815.7	5,015.7	-	-	-	-
Bennicas (Georgia) dba Bennicas And Associates	8,700.0	8,700.0	9,057.1	9,057.1	9,057.1	9,057.1	9,057.1	8,700.0
Berkeley Capital Management	640.0	200.0	375.0	717.1	375.0	494.3	460.0	390.7
Bessemer Group, Incorporated	263,170.0	74,140.7	67,975.0	61,480.0	55,805.0	65,652.9	77,737.9	104,545.0
Beta Management Ltd	24,500.0	-	-	47,300.0	46,800.0	-	-	-
Bidwell (C.M.) & Associates, Ltd.	-	43,490.0	-	-	-	-	-	-
Birinyi Associates Inc.	5,550.0	5,550.0	5,550.0	5,800.0	7,100.0	-	-	-
Blackhill Capital, Inc.	47,600.0	84,400.0	84,400.0	82,400.0	-	72,400.0	106,700.0	70,267.9
Blackrock Inc.	576,400.0	730,677.9	812,814.3	325,064.3	302,064.3	218,024.3	-	-
Blair (William) & Company, L.L.C.	1,318,105.0	1,367,432.1	1,407,752.9	1,357,860.0	1,060,739.3	259,674.3	221,102.9	202,345.7

**Exhibit-16**

**Shares Held by Institutions During the Class Period**

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
Blair, Christopher, R.	24,600.0	-	-	-	-	7,500.0	6,900.0	-
Blue Ridge Capital, L.L.C.	-	-	-	-	-	-	500,000.0	680,000.0
BNP Paribas Arbitrage, Sa	-	-	-	-	-	-	-	135,322.9
BNP Paribas Asset Management, Sas	-	104,925.0	150,347.9	133,935.0	137,935.0	146,080.0	147,400.0	353,520.7
BNP Paribas Equity Strategies Snc	190,990.0	202,400.7	278,917.1	331,452.9	461,459.3	471,015.0	444,785.7	249,879.3
Boone County National Bank	8,795.0	9,907.1	16,182.1	20,682.1	20,707.1	21,457.1	21,917.1	23,087.9
Boone National Svgs & Ln Assoc-dba Edward Jones Tr Co	14,619.3	24,584.3	24,839.3	20,289.3	18,624.3	17,952.1	17,492.1	15,642.1
Boston Advisors, Inc.	511,342.9	355,900.0	321,000.0	208,400.0	172,600.0	136,100.0	177,600.0	167,500.0
Boston Family Office, LLC	15,395.0	16,359.3	16,859.3	21,209.3	21,709.3	23,784.3	25,734.3	17,859.3
Boston Partners-Asset Management, L.P.	-	-	-	-	-	-	-	403,955.0
Bourgeon Capital Management LLC	-	-	-	10,710.0	10,710.0	12,760.0	15,360.0	7,110.0
Bourne Stenstrom Lent Asset Management	-	-	4,100.0	-	4,100.0	-	-	-
Bowman Financial Management Co Inc.	300.0	-	-	-	-	-	-	-
Boyd Watterson Asset Management LLC	-	-	-	7,020.0	-	-	-	-
Boys, Arnold & Company, Inc.	4,500.0	6,607.9	6,922.1	9,564.3	13,429.3	13,830.0	14,137.1	10,582.1
BP P.L.C.	285,000.0	327,750.0	327,750.0	202,750.0	252,750.0	262,750.0	262,750.0	131,150.0
BPI Global Asset Management LLP	-	-	-	63,700.0	-	163,900.0	167,900.0	114,700.0
Bradley, Foster And Sargent, Inc.	14,650.0	16,267.9	16,435.0	18,722.1	23,749.3	24,349.3	17,527.9	11,767.9
Branch Banking & Trust Company (South Carolina)	11,190.7	9,220.0	9,112.9	18,225.7	19,482.1	18,612.1	9,305.7	-
Branch Banking And Trust Company (North Carolina)	64,262.9	91,667.1	106,709.3	160,080.7	150,464.3	125,280.0	65,940.7	56,570.7
Brandywine Trust Company	-	-	-	68,635.7	68,635.7	68,635.7	68,635.7	68,635.7
Brencourt Advisors, LLC	-	-	-	-	-	-	-	4,750.0
Brenton Investments	11,440.0	10,802.1	9,162.1	8,425.7	8,375.7	-	-	-
Bricoleur Capital Management, LLC	-	-	-	-	-	106,000.0	130,500.0	-
Bridger Management LLC	-	-	-	-	-	-	-	119,400.0
Bridges Investment Counsel	29,425.0	30,220.0	31,220.0	31,220.0	30,520.0	30,470.0	30,170.0	29,270.0
Broadmark Asset Management LLC	-	-	-	-	-	-	8,000.0	-
Brown (Alex.) Investment Management, LLC	81,550.0	81,550.0	81,550.0	81,550.0	81,550.0	171,550.0	171,550.0	151,550.0
Brown Brothers Harriman & Co	1,497,622.1	1,497,622.1	1,538,867.9	1,616,555.7	1,607,392.9	1,643,345.0	-	1,425,527.9
Brown Investment Advisory & Trust Company	5,730.0	6,257.1	6,257.1	21,997.1	21,997.1	19,407.1	-	442,392.1
Bryn Mawr Trust Company	20,215.0	22,337.1	21,854.3	21,725.7	21,725.7	21,725.7	21,859.3	21,450.0
Bufka & Rodgers, LLC	4,400.0	-	-	-	-	-	7,075.0	7,895.7
Bunker Capital, L.L.C.	-	-	21,487.9	24,087.9	21,387.9	20,087.9	10,572.9	-
Burke & Herbert Bank And Trust Company	10,300.0	11,837.9	11,837.9	9,037.9	6,837.9	6,837.9	6,837.9	6,837.9
Burney Company (The)	-	-	7,065.7	5,919.3	5,267.1	-	-	-
Burnham Asset Management Corporation	4,600.0	-	-	-	-	-	-	-
Burnham Sullivan & Associates	12,000.0	-	13,050.0	12,750.0	11,550.0	11,000.0	11,300.0	11,600.0
Burridge Group LLC (The)	63,704.3	85,027.9	107,142.9	393,617.1	438,932.9	453,337.1	616,910.0	748,249.3

**Exhibit-16**

**Shares Held by Institutions During the Class Period**

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
Bush (J.) & Company, Incorporated	6,000.0	6,000.0	5,000.0	96,875.0	-	136,600.0	-	-
Bush O'Donnell Investment Advisors Inc	-	-	-	-	-	12,160.0	12,160.0	12,160.0
Butler Wick Asset Management	-	-	-	22,415.0	16,720.7	15,950.7	15,950.7	15,950.7
Cadinha & Company, Inc.	-	-	-	-	-	-	-	-
California State Teachers Retirement System	3,559,410.0	3,444,405.0	3,483,240.0	3,597,360.0	3,693,560.0	3,569,760.0	3,421,090.0	3,773,254.3
California, University of-Regents	7,520,542.1	8,461,514.3	8,461,514.3	8,462,445.7	8,462,445.7	8,564,545.7	8,564,545.7	9,234,545.7
Calpers (California-Public Employees Retirement System)	2,795,000.0	827,699.3	857,399.3	858,699.3	4,983,499.3	4,873,299.3	4,737,299.3	4,981,099.3
Camden Asset Management, L.P.	100,000.0	-	-	-	-	-	-	-
Campbell, Newman Asset Management, Inc.	26,705.7	26,704.3	26,704.3	26,704.3	26,704.3	26,704.3	20,704.3	21,204.3
Canada Life Assurance Company	-	-	-	-	-	-	50,700.0	39,800.0
Canandaigua National Bank & Trust Corporation	5,000.0	6,207.1	6,207.1	6,207.1	-	-	-	-
Cape Ann Savings Bank	-	-	-	-	-	9,115.0	9,115.0	9,115.0
Cape Cod Bank & Trust Company	-	-	3,450.0	3,450.0	-	-	-	-
Capital City Trust Company	1,450.0	450.0	450.0	450.0	550.0	322.9	-	200.0
Capital Guardian Trust Company	-	4,830.0	14,430.0	3,945.0	6,945.0	13,475.7	13,715.7	13,555.7
Capital International, S.A.	11,700.0	-	-	-	-	-	-	-
Capital Investment Services of America, Inc.	-	-	-	-	-	-	-	5,520.0
Capital Management Associates Inc./FL	4,530.0	5,067.1	5,087.1	5,027.1	5,027.1	1,695.0	1,730.0	1,705.0
Capital Management Corporation	7,350.0	6,350.0	6,350.0	7,050.0	23,750.0	17,010.0	18,635.0	17,500.7
Capital Research And Management Company	75,088,650.0	84,003,297.9	74,300,095.0	58,990,295.0	55,690,295.0	55,887,595.0	59,803,595.0	69,982,657.9
Capital West Asset Management LLC	-	47,350.0	1,080.0	-	-	-	-	-
Capstone Asset Management Company	126,280.0	138,209.3	144,607.9	147,237.9	149,297.9	152,577.9	157,227.9	158,552.9
Carlson (DL) Investment Group, Inc.	12,242.9	12,242.9	11,792.9	11,792.9	11,600.0	10,200.0	6,400.0	7,000.0
Carlson Capital, L.P.	492,410.0	492,282.9	492,282.9	476,105.0	476,105.0	-	165,000.0	120,000.0
Carret Asset Management	123,850.0	137,767.9	142,437.1	8,352.1	121,190.0	46,887.1	44,235.7	53,052.9
Castleark Management,L.L.C.	-	-	-	122,000.0	-	-	-	-
Catalyst Investment Management LLC	58,269.3	-	-	-	-	-	-	-
Catawba Capital Management	7,340.0	6,205.0	5,615.0	5,615.0	4,715.0	4,765.0	-	4,765.0
Caterpillar Investment Management Ltd	-	34,084.3	33,384.3	33,884.3	33,884.3	33,484.3	33,884.3	33,684.3
Caxton Associates, L.L.C.	-	-	-	240,000.0	166,800.0	-	-	-
Cazenove Fund Management Ltd	-	-	-	-	302,327.9	325,262.9	315,177.9	351,244.3
CCM Partners	14,404.3	15,670.7	15,670.7	15,670.7	15,670.7	15,670.7	16,870.7	16,870.7
CDC Investment Management Corp	-	28,385.0	25,885.0	14,585.0	27,000.0	33,400.0	-	-
Central Bank & Trust Company	-	-	-	-	-	-	-	-
Central Trust Bank/Mo	3,840.0	4,152.9	4,332.9	4,642.9	5,142.9	5,642.9	4,895.0	4,895.0
Centura Bank	28,400.0	28,225.0	28,225.0	28,225.0	23,225.0	22,525.0	-	-
CGU Asset Management Inc	383,500.0	456,365.0	473,865.0	362,500.0	17,500.0	317,500.0	-	-
Chapman Capital Management, Inc.	5,500.0	3,700.0	30,100.0	23,300.0	26,200.0	21,000.0	-	-

**Exhibit-16**

**Shares Held by Institutions During the Class Period**

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
Charter Oak Partners	-	-	-	-	-	-	600,000.0	600,000.0
Chartwell Investment Partners	-	35,090.0	10,590.0	-	1,938,600.0	1,324,825.0	2,005,590.7	2,456,750.7
Chemical Bank And Trust Company	9,317.1	13,584.3	13,584.3	13,484.3	13,484.3	13,484.3	15,855.7	15,747.1
Chesapeake Partners Management Co Inc./MD	218,614.3	-	281,482.9	281,482.9	-	-	-	-
Chevy Chase Bank	-	-	-	61,452.9	62,052.9	466,065.0	915,655.0	453,414.3
Chicago Asset Management Company	780,545.0	497,062.1	433,730.0	428,987.1	-	-	-	-
Chicago Equity Partners, LLC	-	6,450.0	5,950.0	21,000.0	594,700.0	36,900.0	39,900.0	34,600.0
Chilton Capital Management, L.P.	92,845.0	96,412.9	-	115,802.9	102,677.9	56,385.0	56,832.1	54,570.7
Chilton Investment Co. Inc.	-	-	-	-	-	-	-	2,007,470.0
Chittenden Corporation	28,720.0	29,887.9	31,072.9	30,497.9	36,857.9	27,447.1	24,697.9	24,010.0
Chubb Corporation (The)	-	60,000.0	60,000.0	40,000.0	40,000.0	40,000.0	40,000.0	-
Church Capital Management, Inc.	-	-	-	-	4,135.7	-	-	5,065.0
Churchill Management Corp	-	-	-	3,685.0	-	-	-	-
CIBC World Market Corporation	290,440.7	202,495.7	324,335.0	325,140.7	-	306,410.7	295,514.3	318,720.7
Cigna Corporation	527,719.3	582,197.9	604,649.3	-	-	-	-	-
Citadel Advisors LLC	3,612,500.0	-	-	-	-	336,392.1	287,515.0	-
Citigroup Inc.	17,016,000.0	15,949,859.3	10,524,552.9	11,514,864.3	13,084,069.3	14,709,859.3	15,800,542.1	16,098,984.3
Citizens Bank Wealth Management, N.A.	58,722.1	73,147.9	259,877.9	63,155.7	165,140.0	162,680.0	162,374.3	162,134.3
City Capital Inc.	-	-	-	-	26,709.3	29,304.3	47,440.0	46,710.0
City National Bank, City National Investments	-	30,579.3	10,120.0	9,705.7	11,130.7	11,130.7	12,869.3	11,860.7
Claiborne Capital Management, L.P.	-	-	-	-	-	-	-	150,000.0
Clifford Associates, Inc.	4,100.0	4,000.0	4,000.0	4,000.0	4,000.0	-	-	-
Cna Financial Corporation	-	80,000.0	80,000.0	80,000.0	90,000.0	70,000.0	-	-
Cobblestone Capital Advisors LLC	-	-	3,584.3	4,227.1	4,227.1	-	-	9,565.7
Cogan, John F. Jr., Trustee/Hale And Dorr	9,965.0	7,960.0	7,960.0	7,555.0	2,765.0	2,765.0	2,765.0	2,765.0
Cohen, Klingenstein & Marks Incorporated	2,596,555.0	2,565,877.1	2,478,034.3	2,358,555.0	2,300,335.7	2,235,929.3	2,253,042.1	2,461,270.7
Colonial Management Associates, Inc	50,575.0	52,885.0	54,275.0	36,425.0	-	-	183,800.0	1,349,900.0
Colorado Public Employees Retirement Assn (Pera)	861,600.0	947,092.1	1,153,592.1	939,492.1	896,492.1	870,592.1	941,992.1	853,300.0
Colorado State Bank And Trust	5,500.0	4,800.0	4,800.0	6,180.0	6,180.0	5,150.0	-	5,075.0
Columbia Management Co	370,327.9	4,473,782.9	5,851,354.3	5,047,049.3	5,381,080.0	3,956,305.0	3,513,630.0	2,570,855.0
Columbus Circle Investors	-	373,100.0	1,172,700.0	1,287,375.0	8,085.0	-	-	-
Comerica, Inc.	541,292.1	-	-	-	-	-	-	-
Commerce Bank N.A. (Missouri)	328,950.0	316,415.7	293,150.7	233,977.9	230,370.7	228,422.9	233,107.1	224,562.1
Commerce Bank N.A. (Peoria, Illinois)	8,442.9	8,242.1	8,242.1	8,587.1	8,587.1	8,587.1	1,110.0	1,110.0
Commerce Bank N.A. (Wichita, Kansas)	-	90.0	90.0	-	-	-	-	-
Compass Bank	8,315.0	9,130.7	10,000.7	10,000.7	17,500.7	18,005.7	13,105.0	12,655.0
Concord Investment Company	342,815.0	344,255.7	35,960.0	36,127.1	36,127.1	38,655.0	-	-
Condor Capital Management	32,580.7	5,455.0	-	-	-	-	-	-

**Exhibit-16**

**Shares Held by Institutions During the Class Period**

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
Conestoga Capital Advisors, LLC	-	-	-	-	-	-	-	5,325.7
Connable Office, Inc. (The)	239,505.7	240,005.7	242,002.9	232,047.1	232,247.1	231,985.7	232,485.7	231,760.7
Conning Asset Management Company	93,587.9	216,915.0	172,645.0	190,570.0	132,039.3	134,010.0	132,634.3	130,087.9
Connors Investor Services, Inc.	117,795.0	118,945.7	115,310.7	112,512.1	111,010.7	107,810.0	107,450.0	112,187.9
Conseco Inc.	-	23,810.0	42,730.0	-	-	-	-	-
Cooke & Bieler, Inc	1,000.0	1,000.0	-	-	-	-	-	-
Coolidge, Francis L.	12,325.0	28,465.0	28,465.0	28,465.0	28,465.0	18,112.9	18,112.9	18,112.9
Copper Mountain Trust Company	60,829.3	43,254.3	16,625.0	10,997.1	-	-	-	-
Cornercap Investment Counsel, Inc.	-	-	-	-	-	-	-	10,000.0
Cornerstone Advisors, Inc.	-	-	-	-	-	-	-	11,900.0
Cornerstone Capital Management, Inc.	-	-	-	-	-	-	26,880.0	-
Cornish, John M.	37,840.0	40,237.9	40,237.9	40,562.9	40,282.9	40,282.9	79,565.7	37,832.1
Courier Capital Coporation	26,925.0	-	-	20,512.1	-	-	-	-
Crawford Investment Counsel, Inc.	39,187.9	39,575.0	54,575.0	59,627.9	61,925.0	64,812.9	64,812.9	67,112.9
Credit Suisse Asset Management	6,257,465.7	5,598,977.1	5,822,767.1	4,585,989.3	4,530,427.9	4,424,977.9	4,821,445.7	4,348,457.9
Credit Suisse First Boston Corporation	1,457,864.3	1,708,045.7	1,956,115.0	1,300,522.9	1,060,195.7	982,557.9	916,269.3	1,648,630.7
CSI Capital Management Inc.	26,400.0	26,400.0	26,400.0	26,400.0	26,400.0	28,500.0	29,000.0	29,000.0
Cullen/Frost Bankers, Inc	77,734.3	65,147.9	275,640.7	331,592.1	294,374.3	287,864.3	287,345.0	166,087.9
Cutler & Company, LLC	4,000.0	7,504.3	7,504.3	7,504.3	-	-	-	-
Cypress Asset Management, Inc.	27,310.0	55,830.0	62,940.0	67,490.0	79,325.0	76,725.0	59,915.0	19,845.0
D.A. Davidson & Co.	-	-	-	-	-	-	-	6,555.0
Dai-Ichi Life Insurance Company Limited	349,985.0	312,529.3	310,462.1	350,857.9	312,137.9	309,207.1	356,022.9	71,199.3
Dane, Falb, Stone & Company, Inc.	24,514.3	24,395.0	23,680.7	21,267.9	21,267.9	21,267.9	20,910.7	20,910.7
Dassori (F. Davis), Jr.	40,962.9	38,634.3	-	38,634.3	37,442.1	37,442.1	37,442.1	28,592.1
Davenport & Company LLC/VA	25,227.9	26,124.3	22,845.0	27,340.0	25,995.0	26,642.9	18,994.3	20,385.0
Davidson & Garrard Inc	39,305.7	36,155.0	35,937.1	34,625.7	34,517.9	32,687.9	25,242.9	27,454.3
Davidson Investment Advisors	206,302.1	-	-	-	-	-	-	-
Davidson Trust Company	-	-	-	-	-	-	-	45,099.3
Davidson Trust Company/Pa	6,300.0	6,580.7	6,580.7	6,480.7	6,124.3	6,124.3	5,444.3	5,444.3
Davis Selected Advisers, LP	1,595,000.0	1,619,105.0	1,583,432.1	1,615,809.3	1,580,440.0	1,625,822.1	3,296,772.1	3,469,950.0
Davis, R.M., Inc.	5,960.0	4,800.0	5,000.0	5,315.0	5,309.3	-	-	-
DCF Capital, L.L.C.	524,655.0	277,315.0	412,315.0	207,315.0	12,315.0	12,315.0	125,315.0	-
De Garmo & Kelleher	4,500.0	4,635.0	4,635.0	4,635.0	4,705.0	4,705.0	6,699.3	7,067.1
Dean (C.H.) & Associates, Inc.	-	-	-	-	-	-	14,652.9	13,030.0
Dearden, Maguire, Weaver & Barrett Inc.	4,670.7	-	-	4,270.7	5,790.7	5,855.7	5,357.1	15,282.1
Deephaven Capital Management, LLC	-	-	-	-	-	-	39,000.0	44,400.0
Deere & Company	117,647.1	117,647.1	117,647.1	165,047.1	165,047.1	165,047.1	165,047.1	165,047.1
Delaware Capital Management	155,087.9	-	-	-	-	-	-	-



**Exhibit-16**

**Shares Held by Institutions During the Class Period**

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
Delaware Management Business Trust	2,325,500.0	90,800.0	98,367.1	63,680.7	62,515.0	88,115.0	90,925.0	131,180.0
Deltec Asset Management LLC	-	-	-	-	-	1,250.0	1,250.0	1,250.0
Denver Investment Advisors LLC	12,990.0	37,640.0	45,690.0	46,347.1	50,184.3	58,520.0	52,239.3	74,787.9
Deprince, Race & Zollo, Inc.	158,925.7	-	-	-	-	-	126,100.0	347,900.0
DG Capital Management, Inc.	-	-	-	-	-	-	-	160,000.0
Diamond Capital Management Inc.	-	-	-	-	-	-	-	-
Dimensional Fund Advisors LP	-	338,100.0	341,600.0	346,500.0	346,200.0	363,500.0	361,900.0	392,582.9
Disciplined Investment Advisors	92,500.7	108,632.1	126,292.1	33,519.3	300.0	-	-	-
Dixon, Hubard & Feinour & Brown Inc.	11,125.0	11,860.0	11,860.0	11,560.0	11,560.0	10,760.0	8,575.0	7,250.0
Dlibj Asset Management Co., Ltd.	-	147,614.3	152,415.0	158,590.7	196,215.0	194,362.1	186,652.1	99,257.1
DNB Nor Asset Management (Us), Inc.	-	-	-	-	1,111,060.0	1,134,190.0	685,600.0	717,300.0
Dodge & Cox Inc	7,290,590.7	8,933,967.1	6,314,305.7	6,256,969.3	6,109,872.1	6,441,927.9	8,422,510.0	9,005,642.1
Doerge & Smith Private Advisory, LLC	-	-	-	-	-	-	900.0	1,405.0
Doolittle (William G) Investment Counselor	-	4,730.7	4,730.7	4,730.7	4,730.7	4,730.7	-	-
Dowling & Yahnke Inc.	-	-	-	15,132.1	15,269.3	19,584.3	20,557.9	19,925.7
Dreman Value Management, L.L.C.	8,972.9	8,972.1	8,972.1	8,972.1	8,972.1	8,972.1	8,972.1	19,472.1
Dresdner Bank AG	316,947.1	414,010.7	652,092.9	1,370,567.1	1,194,809.3	1,211,300.7	1,793,480.0	1,877,190.7
Dresdner Rcm Global Investors LLC	-	2,650,797.9	5,435,790.7	8,063,197.1	9,848,222.1	10,730,195.7	11,519,910.0	12,583,952.1
Duff & Phelps Investment Management Company	-	5,925.0	6,310.0	6,310.0	6,230.0	6,660.0	6,930.0	6,930.0
Duncan-Hurst Capital Management	-	230.0	-	-	-	-	-	-
Duncker, Streett & Co., Inc.	-	11,640.0	11,640.0	11,640.0	-	7,000.0	7,000.0	-
Dupont Capital Management	-	-	58,500.0	17,200.0	29,000.0	53,900.0	605,700.0	927,700.0
Duquesne Capital Management, LLC	-	-	400,000.0	100,000.0	-	-	-	-
Eagle Asset Management, Inc.	334,335.7	337,800.0	590,397.9	618,575.0	741,524.3	649,144.3	1,083,192.9	990,137.1
Eastern Bank & Trust Company	-	-	-	3,700.0	-	-	-	5,092.1
Eaton Vance Management	2,523,594.3	2,525,455.0	2,591,335.0	2,613,402.9	2,611,727.9	2,604,867.9	2,604,867.9	3,396,549.3
Edgewood Management Company	4,000.0	5,475.0	5,475.0	5,475.0	5,475.0	5,475.0	5,475.0	5,725.0
Edinburgh Fund Managers PLC	102,912.9	101,309.3	264,984.3	290,499.3	300,189.3	298,359.3	300,859.3	295,945.0
Edwards, A.G., Inc.	15,994.3	67,390.0	90,147.9	85,850.0	77,544.3	81,032.9	84,347.1	84,322.9
EGM Capital	-	-	-	-	-	28,500.0	29,000.0	29,000.0
Ehrman (William)	28,760.7	21,225.0	21,225.0	-	25,000.0	-	-	-
Elias Asset Management Inc.	3,535.0	-	-	-	-	-	-	-
Elliott & Associates, Inc	41,500.0	41,017.1	36,200.0	36,270.7	34,270.7	33,070.7	-	-
Employees Retirement System of Texas	-	458,102.9	813,702.9	1,368,202.9	1,559,500.0	1,185,500.0	1,182,100.0	1,266,100.0
Endex Capital Management LLC	17,612.1	17,562.1	17,612.1	11,190.7	11,190.7	11,190.7	11,190.7	-
Engebretson Capital Management, Inc.	-	-	-	-	-	-	-	385.0
Engemann Asset Management	2,019,994.3	2,376,282.1	3,929,904.3	3,967,195.7	4,153,985.0	2,510,337.1	2,308,702.9	2,195,237.9
Entrust Capital Inc.	-	-	4,195.0	4,195.0	4,195.0	4,545.0	-	-



**Exhibit-16**

**Shares Held by Institutions During the Class Period**

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
Equinox Capital Management	-	-	-	-	-	-	309,400.0	68,500.0
Equitrust Investment Management Services, Inc.	-	-	-	-	-	46,577.1	67,105.0	71,872.1
Essex Investment Management Co Inc	-	-	-	-	-	-	-	-
Estabrook Capital Managemen LLC	23,697.1	23,797.1	25,585.0	26,457.1	25,487.1	26,289.3	24,305.7	24,370.7
Eveans, Bash, Magrino & Klein, Inc.	98,817.9	-	95,520.7	74,470.0	67,492.9	62,477.9	88,245.7	83,994.3
Exxonmobil Investment Management, Inc.	241,695.0	241,195.0	226,805.7	229,790.7	254,102.9	250,202.9	251,582.9	256,325.0
Fahnestock & Company	9,162.9	8,799.3	9,199.3	14,829.3	14,629.3	8,629.3	38,902.9	-
Fairfield Research Corp	-	1,014.3	1,004.3	1,004.3	-	-	-	-
Fairport Asset Management, LLC	-	19,925.0	48,525.0	78,025.0	77,325.0	69,375.0	57,372.9	-
Family Capitl Fiduciary LLC	-	-	-	-	-	-	2,260.0	2,260.0
Farallon Capital Management LLC	1,400,184.3	-	830,424.3	730,300.0	730,300.0	-	-	-
Farrell SI Investment Management Inc.	-	-	18,700.0	18,700.0	-	-	-	-
FCA Corporation	-	-	-	-	-	-	-	15,150.0
Federated Investors, Inc.	2,468,255.0	2,530,412.1	2,630,012.1	2,871,312.1	2,101,622.9	1,894,110.7	1,653,612.1	3,292,270.0
Ferguson, Wellman, Rudd, Purdy & Van Winkle, Inc	17,015.0	18,829.3	17,820.0	17,620.0	18,829.3	17,140.7	16,595.7	16,695.7
Fidgeon, Timothy F.	-	-	-	13,920.0	13,920.0	13,920.0	13,720.0	13,720.0
Fiduciary Asset Management, LLC	11,662.1	8,900.0	112,939.3	20,089.3	18,889.3	24,689.3	24,689.3	137,314.3
Fiduciary Management Associates Inc	119,000.0	68,950.0	152,325.0	153,825.0	96,155.0	-	-	-
Fiduciary Services Corporation	15,027.1	16,280.0	15,377.9	15,377.9	14,782.9	14,782.9	14,690.7	14,345.7
Fiduciary Trust Company (Mass)	101,467.1	101,797.9	105,005.0	103,537.1	103,490.0	104,592.1	104,992.1	104,990.7
Fifth Third Bancorp	307,495.0	304,194.3	306,857.9	314,835.0	5,544,527.1	4,846,300.0	4,697,647.9	2,719,487.1
Fifth Third Bank/Mi	4,316,745.7	5,115,725.7	5,114,372.1	5,064,970.0	5,001,425.0	4,292,429.3	4,145,717.1	-
FIL Ltd	56,340.0	154,310.0	41,532.1	91,340.0	76,485.7	521,085.0	143,200.0	143,200.0
Financial Counselors, Inc.	5,000.0	5,000.0	5,000.0	5,000.0	7,100.0	7,200.0	7,325.0	7,194.3
Financial Management Advisors, Inc.	-	-	-	-	-	83,750.0	74,425.0	30,450.0
First American Trust Company	52,062.9	48,587.9	-	38,410.7	36,335.7	-	-	-
First Citizens Bank & Trust Company	18,920.0	-	682,245.0	-	627,845.0	666,555.7	934,139.3	311,757.1
First Financial Bank, N.A.	17,105.7	-	16,855.7	18,030.0	16,910.0	100,007.1	103,862.1	123,862.1
First Horizon National Corp	47,382.9	46,515.0	58,059.3	77,292.1	115,597.1	147,992.1	191,792.1	168,175.0
First Interstate Bank	15,315.0	16,840.0	17,365.0	16,547.1	19,822.1	17,897.1	19,847.1	19,790.7
First Investors Management Company, Inc	150,715.0	141,214.3	141,214.3	219,814.3	232,000.0	-	335,000.0	324,800.0
First Manhattan Company	-	70,612.1	29,612.1	6,612.1	47,962.1	54,637.9	1,121,942.1	1,131,895.0
First National Bank of Chester County	-	-	-	-	-	-	-	-
First National Bank of Omaha	5,945.0	-	7,309.3	7,309.3	7,309.3	6,359.3	55,819.3	10,025.0
First National Trust Company	-	3,890.0	3,890.0	-	-	-	-	5,735.0
First Quadrant L.P.	78,500.0	130,630.0	29,140.0	29,240.0	124,140.0	31,140.0	31,340.0	34,965.0
First Security Bank	124,815.0	123,635.7	150,694.3	-	-	-	-	-
First Source Bank	16,484.3	15,760.0	15,860.0	15,310.0	15,310.0	15,037.9	15,037.9	15,037.9

## Exhibit-16

### Shares Held by Institutions During the Class Period

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
First State Investment Management Uk Ltd	-	-	6,820.0	-	-	-	-	-
First Virginia Bank	-	7,975.0	10,452.9	9,952.9	14,752.9	21,662.9	25,462.9	27,987.9
Firstmerit Bank N.A., Trustee	137,032.9	135,710.7	133,922.1	148,060.7	157,952.1	161,027.9	168,155.7	157,054.3
Fisher Investments, Inc.	16,980.7	16,580.7	16,592.1	19,279.3	15,244.3	15,365.7	15,990.7	15,410.7
Fishman (Jay A.), Ltd.	1,688,647.9	1,706,880.7	1,675,762.1	1,671,485.0	1,660,172.1	1,895,090.0	1,928,129.3	1,907,974.3
Fleetboston Financial Corporation	3,346,872.1	2,745,045.0	3,626,720.7	3,653,542.1	4,490,357.1	4,969,080.7	5,043,495.7	4,880,597.1
Fleiss, Karen M.	-	-	-	20,000.0	-	-	-	-
Florida State Board of Administration	1,427,302.1	1,691,100.7	1,832,100.7	2,359,100.7	2,508,000.7	2,508,500.7	2,533,300.7	3,165,800.7
FMR LLC	2,137,735.0	18,141,742.9	29,225,312.1	30,424,514.3	14,737,792.1	20,990,450.0	17,879,055.0	27,834,129.3
Forbes, J.M. & Company	33,665.7	-	-	-	20,809.3	-	-	-
Forstmann Asset Management LLC	-	-	-	-	-	-	-	50,500.0
Forstmann-Leff Associates LLC	29,750.0	313,655.7	28,440.7	36,440.7	-	-	-	-
Fort Washington Investment Advisors, Inc.	-	-	-	49,700.0	72,025.0	-	20,725.0	22,725.0
Franklin Resources, Inc	6,379,485.7	6,088,554.3	4,412,589.3	4,427,847.1	5,418,739.3	5,689,394.3	10,197,664.3	10,513,045.0
Franklin Street Advisors, Inc.	246,404.3	3,870.0	-	6,440.0	-	-	-	-
Freeman Associates Investment Management, LLC	17,434.3	97,842.9	159,342.9	79,872.1	60,772.1	60,772.1	55,172.1	54,072.1
Fremont Investment Advisors, Inc.	-	23,000.0	29,000.0	35,970.0	32,970.0	40,970.0	34,832.9	32,760.7
Friends Ivory & Sime, Inc.	-	-	94,100.0	647,250.0	815,040.0	-	-	-
Froley, Revy Investment Company Inc	-	-	-	-	-	-	-	98,724.3
Frontier Capital Management Company Inc	-	-	8,505.0	45,205.0	39,805.0	6,400.0	18,600.0	24,200.0
Frye-Louis Capital Management, Inc.	22,197.9	21,679.3	22,110.0	23,867.1	25,780.0	24,325.7	23,740.7	13,840.7
Fulton Breakefield Broenniman, LLC	-	0.7	-	-	-	-	-	-
Fulton Financial Advisors, NA	33,207.9	40,577.1	41,614.3	20,749.3	17,297.1	17,374.3	18,402.9	18,202.9
Fund Asset Management Inc	10,403,915.0	54,817.9	53,307.1	-	-	-	-	-
Furman Selz Capital Management, LLC.	192,600.0	-	-	-	-	-	141,902.9	156,002.1
Gabelli Funds, LLC	2,367,800.0	80,000.0	80,000.0	75,000.0	72,000.0	72,000.0	72,000.0	72,000.0
Gabriel Capital Corp.	-	-	176,865.7	-	187,544.3	276,295.7	284,704.3	-
Galleon Management L.P.	357,000.0	150,000.0	-	500,000.0	-	-	195,000.0	200,000.0
GAM USA, Inc.	79,000.0	-	-	-	-	-	79,000.0	79,000.0
Gamble Jones Investment Counsel	49,940.0	49,065.0	59,432.1	59,315.0	57,627.1	57,227.1	57,035.7	56,972.1
Gamco Investors Inc	213,730.0	-	-	7,457.1	-	-	-	-
Gannett Welsh & Kotler, Inc.	11,000.0	11,000.0	11,000.0	11,297.1	11,297.1	11,297.1	11,297.1	11,297.1
Gardner Lewis Asset Management, Inc.	-	4,132.1	7,232.1	7,232.1	9,032.1	-	-	-
Gardner Russo & Gardner	-	-	-	-	-	200.0	200.0	500.0
Garrison Institutional Asset Management	30,205.0	54,965.0	58,265.7	84,465.7	88,360.7	89,585.7	53,510.7	83,310.7
Garrison, Bradford & Associates, Inc.	4,750.0	4,750.0	4,750.0	4,500.0	-	-	-	-
Gartmore Investment Management, PLC	-	244,972.9	239,944.3	1,778,725.7	626,357.9	310,429.3	441,254.3	454,699.3
Gartmore Mutual Fund Capital Trust	1,348,600.0	787,165.7	803,699.3	1,481,799.3	420,729.3	96,039.3	183,409.3	191,705.7

**Exhibit-16**

**Shares Held by Institutions During the Class Period**

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
Gateway Investment Advisors, Inc.	198,299.3	204,764.3	223,730.0	223,237.9	242,682.1	231,515.7	228,087.9	206,620.0
Geewax, Terker & Company	26,440.0	34,662.1	34,552.1	1,823,155.7	1,278,430.0	805,440.0	205,050.0	-
General Electric Company	1,941,475.7	2,144,840.0	1,845,860.0	1,816,365.7	1,797,642.9	1,809,645.0	2,118,697.1	3,451,019.3
General Motors Investment Management Corporation	305,815.7	363,494.3	192,210.7	192,284.3	193,584.3	192,384.3	116,684.3	33,984.3
General Re-New England Asset Management, Inc.	2,300.0	-	4,100.0	3,690.0	2,490.0	5,890.0	5,890.0	8,712.9
Gilkison Patterson Investment Advisors Inc	18,235.7	18,532.1	18,532.1	18,460.0	18,460.0	18,287.9	18,287.9	21,132.1
Glenmede Trust Company (The)	176,310.0	-	178,480.7	381,812.9	348,132.9	263,975.0	226,209.3	202,647.1
Glens Falls National Bank & Trust Company	7,070.0	6,970.0	7,770.0	7,370.0	6,670.0	5,670.0	5,470.0	-
Glenview Capital Management, LLC	-	-	-	-	-	-	-	705,000.0
Global Strategy Financial Inc.	-	-	-	92,000.0	-	-	-	-
Globeflex Capital, L.P.	-	-	35.0	35.0	3,110.0	-	-	-
Glynn (J.A.) & Co.	11,812.1	11,192.1	11,942.1	-	-	-	-	-
Gofen & Glossberg LLC	78,072.1	73,669.3	72,319.3	69,632.9	70,767.1	69,194.3	66,394.3	66,094.3
Golden Capital Management, LLC	-	-	-	-	-	3,500.0	-	3,500.0
Goldman Sachs Group Inc	2,267,462.9	1,540,452.1	1,621,392.9	1,975,309.3	1,942,442.9	1,698,040.0	1,038,449.3	1,063,517.1
Grantham Mayo Van Otterloo & Company	122,960.0	146,959.3	353,759.3	746,559.3	608,740.7	23,540.7	43,240.7	10,000.0
Greenleaf Trust	161,560.0	191,817.9	189,837.1	187,497.1	209,797.9	396,100.7	364,975.0	2,036,319.3
Greenwood Capital Associates, Inc.	-	-	3,425.0	-	-	-	-	-
Greystone Investment Management, LLC	-	-	-	-	-	-	-	-
Gries Financial Inc	-	-	-	12,200.0	12,300.0	12,300.0	-	-
Griffin Asset Management LLC	12,820.0	15,254.3	15,254.3	19,025.0	19,025.0	19,025.0	20,625.0	-
Gruntal & Co., L.L.C.	-	15,225.0	15,609.3	23,344.3	23,162.9	23,769.3	19,079.3	19,747.9
Guaranty Trust Company of Missouri (The)	134,369.3	139,027.9	138,689.3	140,487.1	137,947.9	137,294.3	143,665.7	144,720.7
Guardian Investor Services LLC	15,515.0	31,472.1	51,025.0	51,025.0	51,025.0	74,035.7	78,884.3	78,884.3
Guyasuta Investment Advisors Incorporated	5,450.0	5,450.0	5,050.0	5,050.0	5,922.9	7,902.9	8,412.9	10,372.9
Gw Capital Management, LLC	306,152.1	361,722.9	372,097.9	359,172.9	325,855.0	276,650.7	263,454.3	248,979.3
Haberer Registered Investment Advisor, Inc.	5,725.0	7,227.9	7,227.9	6,967.9	7,022.9	6,687.9	6,687.9	6,204.3
Hale & Dorr Capital Management, LLC	-	-	-	-	-	-	-	-
Halsey Associates, Inc.	42,460.0	74,960.0	75,985.0	75,435.0	75,485.0	75,585.0	92,360.0	99,760.0
Hammer (Roy A.) Esq	12,700.0	13,400.0	23,780.7	23,537.9	23,232.9	21,524.3	18,024.3	-
Hancock Bank Trust Department	8,240.0	8,240.0	8,240.0	8,990.0	8,890.0	8,890.0	8,740.0	-
Handelman (Meyer) Company	-	395,255.7	393,297.9	392,897.9	379,597.9	372,112.9	372,112.9	372,112.9
Hansberger Global Investors, Inc.	79,730.0	4,165.0	4,165.0	4,165.0	4,165.0	48,665.0	51,265.0	69,165.0
Harbor Capital Management Inc	-	11,480.0	16,980.0	16,980.0	16,400.0	16,400.0	18,700.0	16,400.0
Harris,Bretall,Sullivan & Smith, L.L.C.	-	-	11,900.0	-	1,865,860.7	1,673,895.7	1,652,182.1	498,739.3
Hartford Investment Management Company Inc.	343,715.0	375,217.9	375,817.9	399,817.9	367,717.1	370,917.1	368,917.1	427,075.7
Harvard College (President & Fellows of)	1,175,427.9	1,426,310.0	1,326,310.0	532,310.0	283,310.0	792,910.0	652,600.0	157,047.9
Harvest Management, LLC	495,600.0	-	-	-	-	-	-	-

**Exhibit-16**

**Shares Held by Institutions During the Class Period**

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
Haven Capital Management Inc	22,134.3	22,134.3	25,134.3	23,349.3	17,349.3	17,349.3	17,349.3	18,149.3
Henderson Fund Management PLC	-	-	-	-	-	-	1,198,237.1	-
Henssler (G.W.) & Associates, Ltd.	-	-	-	-	-	-	-	-
Heritage Investors Management Corporation	3,420.0	-	-	-	-	-	-	-
Hermes Pensions Management Ltd	-	438,837.9	389,947.1	365,552.9	365,552.9	-	-	-
Hester Capital Management, L.L.C.	28,600.7	34,930.7	33,770.0	34,270.0	34,920.0	34,820.0	-	-
Hibernia National Bank	152,032.9	124,815.7	87,825.0	71,270.0	60,870.0	55,025.0	43,257.9	37,702.9
High Point Bank & Trust Company	-	-	-	-	-	7,122.1	7,122.1	6,922.1
Highland Capital Management Corporation	18,314.3	18,020.0	47,170.0	567,410.0	904,065.0	1,235,695.0	1,525,552.1	1,599,167.1
Highline Capital Management, LLC	-	-	-	-	-	-	-	146,700.0
Hintz, Holman & Hecksher, Inc.	-	-	569,700.0	-	-	-	-	-
Holderness Investments Company	-	-	-	-	-	-	33,204.3	36,425.0
Holland Capital Management, LLC	-	73,687.9	73,837.9	78,087.9	78,137.9	99,940.0	174,265.0	306,450.0
Horizon Asset Management, Inc./NY	10,320.7	10,620.7	10,620.7	10,545.7	9,945.7	13,245.7	35,430.0	47,589.3
Howard Capital Management	8,060.0	8,000.0	35,400.0	54,700.0	51,300.0	51,300.0	26,500.0	23,200.0
Howard Hughes Medical Institute	416,500.0	70,000.0	120,000.0	60,000.0	-	-	-	-
Howland Capital Management	-	3,940.0	3,640.0	3,640.0	-	-	-	-
HSBC Bank USA - IM	-	-	3,550.0	3,550.0	-	-	-	-
HSBC Holdings PLC	365,785.0	279,195.0	278,417.9	307,722.9	326,709.3	437,865.7	497,325.0	591,622.1
Hughes Investment Management Company	-	2,000.0	2,000.0	2,000.0	2,000.0	1,000.0	-	-
Huntington National Bank	238,240.7	263,842.1	254,594.3	185,745.7	146,890.0	134,635.0	135,910.7	141,705.0
Husic Capital Management	-	6,300.0	-	-	-	-	-	-
HVB Capital Management, Inc	16,699.3	-	-	10.7	10.7	-	-	-
I.G. Investment Management, Ltd	18,400.0	21,895.7	21,895.7	21,895.7	23,195.7	21,895.7	49,395.7	88,845.7
IBM Retirement Plan	1,009,714.3	942,072.1	943,985.7	959,182.1	1,011,865.7	991,390.0	1,009,510.0	1,001,499.3
ICC Capital Management, Inc.	137,000.0	117,000.0	68,200.0	-	-	-	1,132.1	-
Independence Investment LLC/Ma	5,012,247.9	4,670,355.7	5,902,914.3	3,064,870.0	2,025,900.0	1,819,500.0	2,989,300.0	2,654,900.0
INGg Advisors, Inc.	-	-	-	-	11,717.9	11,717.9	8,917.9	-
ING Investment Management Advisors B.V.	-	-	-	2,700.0	2,200.0	-	-	630.0
ING Investment Management, LLC.	45,000.0	-	-	92,220.0	52,700.0	-	-	-
ING Investments, LLC	120,500.0	157,679.3	34,700.0	39,420.0	25,400.0	27,800.0	179,900.0	179,420.0
Ingalls & Snyder	101,577.1	88,740.0	17,015.7	16,615.7	16,550.7	17,455.7	17,180.7	21,120.7
Innovest Capital Management	-	18,600.0	27,600.0	29,000.0	32,100.0	32,100.0	31,800.0	65,000.0
Institutional Capital Corporation	3,186,300.0	6,081,714.3	5,701,705.7	5,267,785.0	6,918,160.7	7,855,470.7	8,733,777.9	-
Insurance Company of The West	-	-	-	-	-	-	-	-
Integra Bank N.A.	-	4,337.9	4,337.9	4,337.9	4,100.0	-	-	-
Intel Corporation	220,972.1	277,829.3	278,129.3	278,129.3	332,929.3	380,829.3	405,229.3	395,729.3
Intrepid Capital Management Inc/NY	170,365.0	155,745.7	113,137.1	105,490.7	121,800.0	139,712.9	157,115.7	174,404.3

**Exhibit-16**

**Shares Held by Institutions During the Class Period**

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
Inverness Counsel, LLC	5,040.0	5,897.9	5,607.9	-	-	5,707.9	-	4,707.9
Invesco Asset Management Ltd.	-	-	-	1,178,977.9	2,512,250.0	2,229,817.9	1,828,527.1	2,077,317.9
Invesco Funds Group, Inc.	3,141,100.0	2,298,222.9	5,360,522.9	5,829,122.9	5,776,162.9	3,606,667.1	2,885,994.3	5,050,774.3
Invesco Institutional (N.A.), Inc.	989,307.9	1,531,702.9	5,777,100.0	4,935,435.0	5,558,725.7	5,172,730.0	4,397,599.3	4,317,275.0
Investment Counselors of Maryland	16,450.0	7,450.0	15,450.0	15,450.0	15,450.0	15,450.0	15,450.0	6,350.0
Investment Management of Virginia LLC	-	-	-	-	-	-	-	6,120.0
Irvine Capital Management, LLC	-	-	-	-	-	10,000.0	15,000.0	-
Jacobs & Company	16,172.1	17,367.1	17,367.1	17,367.1	17,267.1	16,367.1	16,134.3	13,509.3
Jacobs Levy Equity Management, Inc.	87,800.0	821,594.3	-	8,700.0	27,300.0	16,700.0	8,100.0	1,034,170.0
JAM Asset Management, L.P.	54,859.3	39,204.3	-	-	-	-	-	-
Janus Capital Management, LLC	1,356,650.0	15,208,625.0	14,463,075.0	11,651,310.0	11,455,937.9	7,678,182.9	5,455,827.1	3,786,964.3
Jemmco Investment Management LLC	-	-	-	-	11,600.0	-	-	6,000.0
Jennison Associates LLC	8,724,000.0	17,773,254.3	13,785,255.0	14,782,735.0	14,722,872.1	13,794,547.9	13,512,837.1	12,633,907.9
Jensen Investment Management, Inc.	2,610.0	-	2,160.0	2,160.0	2,160.0	2,535.0	2,235.0	2,235.0
JL Advisors, LLC	-	-	-	-	-	-	-	292,395.7
Jmc Capital Management, Inc.	24,150.0	-	-	-	-	-	-	-
John Hancock Advisers, Inc.	587,720.0	625,782.9	1,076,270.0	917,704.3	1,180,357.1	789,780.7	1,205,092.1	1,202,012.1
Johnson (Tom) Investment Management, Inc.	4,765.0	-	-	-	-	-	-	-
Johnson Investment Counsel, Inc.	22,790.7	23,895.7	24,715.7	24,402.9	24,227.9	25,130.7	25,105.7	25,300.7
Johnston, Reid & Mitchell, Inc.	25,402.1	28,397.9	-	24,697.9	25,097.9	24,097.9	24,097.9	23,097.9
JP Morgan Chase & Company	31,933,790.7	28,847,570.7	27,173,600.0	20,733,352.1	18,135,282.9	24,070,240.7	22,596,182.9	17,270,927.9
Jundt Associates, Inc.	1,009,395.0	887,995.0	900,554.3	894,754.3	339,654.3	336,154.3	382,554.3	382,654.3
Jurika & Voyles LP	457,905.0	423,739.3	408,712.1	390,872.1	413,907.1	433,375.7	768,592.1	750,357.9
Kahn Brothers & Company, Inc.	196,619.3	190,524.3	173,030.7	171,995.7	170,699.3	171,114.3	170,422.9	169,090.7
Kayne Anderson Rudnick Investment Management LLC	7,140.0	5,700.0	6,092.1	-	-	-	5,185.0	4,992.1
KBW Asset Management Inc.	-	-	-	-	1,000.0	-	-	-
KCM Investment Advisors LLC	6,500.0	17,380.0	18,080.0	16,565.7	34,240.0	30,240.0	30,240.0	8,100.0
Keating Investment Counselors	37,100.0	35,600.0	35,600.0	34,440.0	34,440.0	32,940.0	32,705.0	32,705.0
Keller Group Investment Management, Inc.	-	-	3,500.7	-	26,394.3	214,200.7	284,715.0	280,059.3
Kellner, Dileo & Company	205,700.0	-	-	-	-	-	-	-
Kelly (Lawrence W.) & Associates Inc.	-	-	-	-	-	-	-	46,000.0
Kennedy Associates, Inc	303,687.9	228,114.3	-	-	-	-	-	-
Kentucky (State Of) Teachers Retirement System	864,742.9	578,842.9	578,842.9	578,842.9	676,342.9	626,342.9	580,742.9	593,142.9
Keybank National Association	63,972.9	1,177,847.9	1,259,517.1	1,167,132.1	1,471,335.7	2,863,715.0	3,541,239.3	5,301,270.0
Keydel, Frederick, R.	6,960.0	8,282.1	8,282.1	8,282.1	-	-	-	-
Killian Asset Management Corporation	65,120.0	77,492.1	75,055.7	-	-	74,580.0	96,580.0	-
Kinetics Asset Management Inc.	21,539.3	22,539.3	27,539.3	29,539.3	29,539.3	29,539.3	29,539.3	32,539.3
Kingdon Capital Management LLC	-	-	-	-	-	4,500.0	-	-

**Exhibit-16**

**Shares Held by Institutions During the Class Period**

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
Kirkbride Asset Management, Inc.	11,160.0	11,160.0	11,160.0	11,160.0	11,160.0	11,000.0	10,900.0	17,700.0
Klingenstein, Fields & Company, LLC	256,890.0	271,365.0	274,215.0	273,897.1	279,547.1	283,497.1	280,197.1	309,580.7
Kobrick Capital Management, L.P.	-	-	74,300.0	-	-	-	-	-
Kobrick Funds LLC	-	-	62,600.0	56,500.0	-	-	-	-
Kramer Capital Management, Inc.	-	-	-	-	-	-	-	1,400.0
Lafer Management Corp.	-	-	-	-	-	110,000.0	-	-
Laird, Norton Tyee Trust Company	32,135.0	20,435.0	19,160.0	17,660.0	16,360.0	16,360.0	35,277.9	43,147.9
Lane (Douglas, C.) & Associates, Inc.	-	112,637.1	121,662.9	126,682.9	129,622.9	140,704.3	163,477.1	194,587.1
Lasalle Bank N.A.	544,604.3	564,107.1	481,289.3	558,980.7	568,754.3	595,925.0	15,095.7	61,025.0
Lateef Investement Management	-	-	-	-	-	-	-	5,025.0
Lawson Kroeker Investment Management, Inc.	69,675.0	74,700.0	87,650.0	88,060.0	88,160.0	93,535.0	92,685.0	92,335.0
Lazard Freres & Co LLC	2,775,209.3	2,840,882.1	2,110,932.1	1,193,967.9	3,240,500.0	3,478,790.7	3,931,984.3	3,703,982.9
Leavell Investment Management, Inc.	22,457.1	30,882.9	24,457.1	24,457.1	28,127.1	28,957.1	21,457.1	20,215.7
Ledyard National Bank	5,637.1	5,637.1	5,637.1	6,037.1	5,680.0	6,099.3	5,780.0	6,077.1
Lee, Danner & Bass, Inc.	10,240.0	10,907.9	-	-	-	-	-	-
Legal & General Group PLC	755,550.0	21,140.7	20,377.1	26,377.9	26,407.9	7,986,817.9	24,610.7	-
Legg Mason Inc.	718,679.3	652,655.0	611,429.3	550,645.0	662,750.7	656,005.0	673,787.1	862,039.3
Lehman Brothers Holdings Inc.	20,654.3	31,012.9	43,427.1	69,549.3	90,675.7	72,495.0	139,212.9	189,542.9
Lepercq, De Neufelize & Co Incorporated	56,644.3	62,907.1	62,907.1	39,257.1	-	-	-	-
Levin (John A.) & Company, Inc.	3,632,732.9	3,195,870.7	3,424,455.7	3,590,222.9	3,980,482.1	4,555,387.9	4,831,734.3	5,042,330.0
Liberty Mutual Group Inc.	27,500.0	33,825.0	36,425.0	36,425.0	4,500.0	4,500.0	4,500.0	-
Lilley & Company	11,250.0	11,875.0	10,712.1	11,912.1	13,232.1	14,332.1	14,362.1	14,712.1
Lincoln Capital Management Co	18,942,100.0	7,489,500.0	8,746,499.3	5,579,899.3	-	-	-	-
Lindner Asset Management Inc.	7,972.9	51,800.0	52,200.0	110,000.0	28,900.0	-	-	1,600.0
Lipper, Kenneth	-	-	-	340,500.0	-	37,400.0	-	-
Lloyds Banking Group PLC	-	-	-	-	-	-	-	631,157.9
Lodestar Investment Counsel Inc/IL	16,165.7	15,875.7	13,875.7	13,875.7	-	-	-	-
Loeb Arbitrage Management Inc.	49,200.0	72,394.3	-	-	-	-	-	-
Logan Capital Management, Inc.	-	92,584.3	92,584.3	92,584.3	92,645.7	92,685.7	92,990.7	91,677.1
Lomax, Edgar Company (The)	7,700.0	15,650.7	22,250.7	-	-	-	-	-
Lone Pine Capital, LLC	-	535,000.0	535,000.0	535,000.0	-	-	-	-
Longwood Investment Advisors, Inc.	-	-	-	-	-	-	700.0	-
Loomis Sayles & Co L P	2,360,905.7	2,616,902.9	2,708,805.7	2,193,915.7	750,472.9	560,410.7	282,764.3	151,439.3
Lord Abbett & Co	5,508,934.3	4,594,240.0	4,668,312.1	-	2,192,424.3	2,265,830.0	1,752,127.9	1,770,490.7
Loring, Wolcott & Coolidge Fiduciary Advisors	40,855.7	37,350.0	37,245.7	36,465.0	38,245.7	38,979.3	35,379.3	36,402.9
Los Angeles Capital Management & Equity Research, Inc.	115,320.0	95,965.7	81,065.7	95,965.7	95,865.7	409,365.7	448,500.0	438,400.0
Lotsoff Capital Management	-	-	-	-	252.9	252.9	12,152.9	15,597.1
Lowe, Brockenbrough & Company, Inc.	-	5,275.0	5,000.0	5,000.0	4,900.0	4,900.0	199,150.0	289,045.0



**Exhibit-16**

**Shares Held by Institutions During the Class Period**

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
Lowell, William A.	39,560.0	17,890.0	47,890.0	17,890.0	17,890.0	17,702.9	17,702.9	17,567.9
LSV Asset Management	804,797.1	576,895.7	-	-	-	16,100.0	800.0	800.0
Lunn Partners, LLC	20,700.0	24,632.9	24,632.9	-	-	-	-	-
Luther King Capital Management	2,045,260.7	2,407,494.3	2,490,367.9	1,984,945.0	1,283,695.0	1,190,212.9	1,052,699.3	990,720.7
LVM Capital Management Ltd/MI	-	4,244.3	4,937.9	5,490.7	-	4,712.1	5,989.3	6,352.1
M&T Bank	178,030.0	168,902.9	174,277.1	112,042.1	120,830.7	112,597.1	96,885.0	119,259.3
Mackenzie Financial Corporation	26,900.0	49,247.1	146,827.1	160,537.9	162,182.9	-	104,539.3	113,200.0
Mainstream Investment Advisers, LLC	-	-	-	15,000.0	-	-	-	-
Mairs & Power Inc	6,120.0	6,120.0	6,120.0	6,120.0	6,120.0	7,575.7	6,975.7	5,590.7
Manning & Napier Advisors Inc	18,487.1	-	249,390.7	1,724,597.1	2,972,272.1	3,207,457.1	3,651,132.1	3,580,107.1
Manufacturers Life Insurance Co	530,822.9	246,484.3	248,100.7	123,337.1	408,399.3	223,442.9	245,879.3	264,370.7
Manulife Asset Management (North America) Limited	182,384.3	18,475.0	20,729.3	89,829.3	312,805.0	201,410.7	264,367.9	271,030.7
Marco Investment Management LLC	-	-	-	65.0	4,115.0	3,415.0	3,415.0	3,415.0
Markel Gayner Asset Management Corporation	-	15,900.0	15,900.0	15,900.0	15,900.0	33,920.0	33,920.0	33,920.0
Markston International, LLC	120,020.0	120,019.3	104,819.3	86,919.3	78,435.0	78,435.0	78,435.0	78,435.0
Marque Millennium Capital Management Ltd	15,000.0	-	15,000.0	15,000.0	15,000.0	15,000.0	-	-
Marshall & Ilsley Corporation	82,817.9	43,842.1	43,389.3	48,644.3	46,075.7	41,670.0	43,637.9	170,619.3
Marshfield Associates	1,050.0	-	-	-	-	-	-	-
Martin Currie Inc	-	-	-	-	33,000.0	15,000.0	17,200.0	8,600.0
Martin Currie Investment Management Limited	-	-	-	-	184,100.0	115,225.0	74,300.0	74,300.0
Martingale Asset Management, L.P.	-	80,100.0	65,500.0	-	9,000.0	26,000.0	25,700.0	-
Marvin & Palmer Associates, Inc.	-	-	-	172,900.0	-	-	-	-
Massachusetts Financial Services Co - Other	30,455,669.3	-	26,161,882.1	20,308,255.0	21,693,657.9	12,276,732.9	15,189,460.7	2,823,180.7
Massachusetts Institute of Technology	2,575.0	-	-	-	-	-	-	-
Mastrapasqua & Associates	475,134.3	650,047.1	771,412.1	1,025,952.9	1,135,835.0	1,156,075.7	1,077,972.1	480,502.1
Matrix Asset Advisors, Inc.	110,992.9	133,772.1	133,112.1	132,270.7	148,985.7	154,485.0	171,735.7	176,782.9
Maverick Capital Ltd.	-	-	-	-	-	-	-	4,750,000.0
Mc Lean Budden Ltd	-	-	-	-	-	2,500.0	-	-
McGahan Greene Mchugh Capital Management, LLC	78,100.0	138,100.0	138,100.0	138,100.0	138,100.0	138,100.0	138,100.0	138,100.0
Mcglinn Capital Management, Inc.	15,090.0	-	7,142.9	-	-	-	-	142,700.0
McKee (C.S.) L.P.	45,339.3	130,989.3	106,035.0	98,872.1	-	-	136,100.0	223,400.0
McKinley Capital Management, Inc.	-	-	-	663,720.7	666,690.7	652,070.7	546,420.7	264,270.0
McMillion Capital Management, Inc.	600.0	3,284.3	44,515.7	44,787.1	45,789.3	-	-	-
McMorgan & Company	2,117,225.0	2,132,500.0	2,104,035.7	2,149,985.7	2,173,835.7	2,205,235.7	2,658,235.7	2,669,685.7
McRae Capital Management	-	4,212.9	3,812.9	3,812.9	-	-	-	-
Mechanics Bank-John Rubin	5,657.9	5,657.1	5,657.1	5,657.1	5,657.1	5,657.1	8,007.1	8,007.1
Media One Group Inc.	556,925.7	595,090.0	-	-	-	-	-	-
Meeder Asset Management, Inc.	3,680.0	7,180.0	7,180.0	7,370.0	8,340.0	8,450.0	5,980.0	-

**Exhibit-16**

**Shares Held by Institutions During the Class Period**

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
Mellon Bank, N.A.	11,301,517.1	16,057,135.0	17,937,555.0	17,736,984.3	18,319,715.0	17,716,834.3	21,807,024.3	21,145,625.7
Members Capital Advisors, Inc.	746,694.3	864,164.3	403,282.9	410,782.9	513,182.9	703,382.9	915,282.9	959,482.9
Mercantile Bankshares Corporation	25,290.0	33,452.1	31,287.1	32,562.9	36,845.0	39,347.9	40,272.1	35,280.0
Mercantile National Bank of Indiana	-	-	10,359.3	14,680.0	18,900.0	16,302.9	13,112.9	16,912.9
Merlin Biomed Group, L.L.C.	155,000.0	-	-	-	-	-	-	-
Merrill Lynch & Co., Inc.	773,175.0	643,152.9	770,632.1	2,031,354.3	1,222,744.3	1,632,385.7	1,482,132.9	1,480,372.9
Merrill Lynch Investment Managers Co. Ltd. (Japan)	64,084.3	-	-	-	692,349.3	783,879.3	659,457.1	720,157.1
Merrill Lynch Investment Managers Group Limited	1,138,812.9	95,822.1	102,962.1	98,162.1	2,915,162.9	3,309,282.1	3,327,865.7	1,225,547.9
Merrill Lynch Investment Managers, LLC	-	6,126,330.0	10,521,527.1	10,863,549.3	6,633,137.1	5,306,480.0	4,981,292.9	4,951,495.0
Mesirow Asset Management, Inc.	-	-	1,975.0	1,975.0	-	-	-	-
Messner & Smith Theme/Value Investment Management	-	4,000.0	-	4,000.0	4,000.0	-	-	-
Metlife	585,335.0	893,760.0	909,735.0	900,819.3	784,809.3	804,862.1	937,272.1	793,620.7
Metropolitan West Capital Management, LLC	322,585.7	465,492.9	11,792.1	10,347.9	-	-	-	-
Michigan (State of) State Treasurer	1,114,979.3	5,000,372.1	5,008,972.1	5,029,672.1	5,034,002.1	5,040,122.9	5,040,122.9	5,059,822.9
Midas Management Corporation	-	-	-	30,900.0	-	-	-	-
Middleton & Company, Inc.	-	-	3,600.0	3,600.0	-	-	-	-
Milbank Winthrop & Co.	4,360.0	5,787.9	5,787.9	5,787.9	5,787.9	5,787.9	5,787.9	9,537.9
Millennium Partners LP	-	-	-	135,659.3	-	-	-	282,874.3
Minis & Company, Inc.	16,140.0	16,140.0	16,140.0	16,140.0	16,140.0	15,740.0	15,740.0	15,740.0
Missouri State Employees' Retirement System	149,130.0	166,845.7	168,245.7	167,045.7	161,845.7	161,845.7	135,545.7	114,890.0
Missouri Valley Partners, Inc.	-	-	-	4,860.7	5,965.7	4,465.7	-	-
Monetary Management Group, Inc.	-	-	-	5,625.0	-	-	-	-
Monroe Bank & Trust Company, Mi	20,617.9	23,715.7	22,970.7	12,039.3	11,909.3	11,909.3	8,952.1	8,952.1
Montag & Caldwell, Inc.	-	-	9,489,260.0	18,140,087.1	20,261,472.1	14,708,229.3	9,260,575.7	11,180,627.1
Montag (A) & Associates	-	-	3,517.1	3,517.1	-	-	-	-
Montana Board of Investments	-	-	521,600.0	521,600.0	621,600.0	-	-	871,600.0
Montgomery Asset Management, LLC	123,425.0	143,985.7	139,385.0	166,985.7	-	50,170.7	-	-
Moody National Bank Trust Division	-	-	-	-	-	-	-	-
Moody, Lynn & Co.	7,979.3	45,590.0	135,845.0	134,564.3	49,049.3	42,710.7	41,505.7	139,457.1
Moore Capital Management, LLC	-	314,400.0	-	-	-	-	-	-
Morgan Stanley	2,720,027.1	15,321,452.9	16,203,872.9	18,066,720.7	15,181,255.7	13,704,055.0	12,628,024.3	15,257,344.3
Morgens Waterfall Vintiadis & Co. Inc.	-	-	-	66,400.0	-	-	-	-
Morse, Williams & Company, Inc.	24,400.0	-	10,500.0	14,300.0	17,700.0	21,600.0	15,200.0	16,700.0
Mott (Charles, S.) Foundation	154,270.0	165,910.7	165,910.7	165,910.7	165,910.7	165,910.7	165,910.7	165,910.7
Munder Capital Management, Inc.	2,113,339.3	1,433,717.1	1,405,927.9	1,498,085.7	1,514,017.9	1,309,920.7	1,291,839.3	1,316,120.0
Munich Re Capital Management Corp	-	55,975.0	55,975.0	56,000.0	74,300.0	280,087.1	316,387.1	339,287.1
Murphy Capital Management Inc.	6,082.9	1,205.0	5,055.0	7,227.9	5,527.9	4,227.9	1,992.1	1,292.1
Murray Johnstone International Ltd	-	-	20,000.0	46,000.0	-	-	-	-



**Exhibit-16**

**Shares Held by Institutions During the Class Period**

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
Mutual of America Capital Management Corp	139,990.0	236,537.1	269,755.7	132,560.0	128,487.1	131,122.1	128,077.1	130,604.3
MWN Ltd.	-	-	-	-	-	103,000.0	23,500.0	4,840.7
Myers (James M.) Research, Inc.	-	-	-	-	180,859.3	173,669.3	154,705.7	92,475.0
Nagle (Garrett) & Co., Inc.	10,865.0	7,140.0	7,140.0	7,140.0	-	-	-	-
Narragansett Management, LP	-	-	-	-	-	-	-	100,000.0
National Asset Management	-	-	-	2,790.0	79.3	-	-	-
National Bank of Indianapolis Corp	-	-	882.1	2,587.1	2,687.1	3,407.9	3,232.9	4,027.9
National City Corporation	6,419,157.1	8,237,017.9	7,639,799.3	7,676,389.3	7,792,327.1	7,523,625.0	7,635,040.0	7,015,672.1
National Commerce Financial Corp	41,640.0	55,752.1	113,717.9	62,365.7	69,790.7	78,150.7	84,730.0	88,489.3
National Fiduciary Services, N.A.	10,024.3	25,122.9	28,042.9	32,842.9	35,897.9	20,277.9	20,667.9	18,147.9
National Investment Services, Inc.	-	-	178,400.0	60,400.0	-	-	-	-
National Life Insurance Co	1,252,712.9	853,210.7	606,480.7	396,222.9	341,532.1	26,162.9	25,307.1	419,407.1
National Rural Electric Cooperative Association	395,000.0	470,050.0	134,450.0	-	-	-	-	-
Nationwide Mutual Insurance Co	541,600.0	-	-	-	-	-	-	-
NBT Bank, N.A.	35,382.9	34,887.1	34,887.1	34,887.1	33,387.1	33,387.1	33,387.1	33,737.1
NCM Capital Management Group, Inc.	-	-	210,067.1	401,630.7	412,259.3	606,227.1	228,000.0	228,000.0
Needelman Asset Management, Inc.	-	-	-	17,900.0	22,900.0	-	-	-
Nelson Capital Management Inc./Ca	-	4,775.0	4,377.1	4,032.1	-	-	-	-
Neuberger Berman Group, LLC	1,536,845.0	1,925,744.3	1,838,972.1	930,217.1	1,254,652.9	1,540,912.1	1,771,359.3	3,593,142.1
Neville, Rodie & Shaw, Inc	15,875.0	15,872.9	15,907.9	15,610.7	15,280.0	15,180.0	15,080.0	15,215.0
New Mexico Educational Retirement Board	157,374.3	154,374.3	154,374.3	154,374.3	172,674.3	345,347.9	-	188,074.3
New York Life Investment Management LLC	190,509.3	1,192,795.0	1,314,912.1	2,725,075.7	1,354,847.9	1,267,735.7	1,260,080.7	1,189,310.0
New York State Common Retirement Fund	5,749,485.0	6,600,020.0	5,294,025.7	5,208,525.7	5,439,925.7	5,524,185.7	3,790,820.0	4,162,679.3
Newell Associates	678,994.3	751,339.3	569,537.9	544,437.9	544,437.9	544,437.9	544,437.9	546,737.9
Niagara Investment Advisors, Inc.	13,892.9	15,902.1	16,060.0	24,417.1	26,025.7	24,887.9	24,127.1	21,232.1
Nicholas Company, Inc.	423,000.0	825,470.0	825,470.0	823,370.0	812,870.0	812,070.0	803,770.0	803,770.0
Nichols & Pratt Advisors, LLP	-	-	-	-	-	-	7,315.0	7,315.0
Nippon Life Insurance Company	495,800.0	-	-	1,494,487.9	1,809,415.0	1,703,899.3	1,591,609.3	-
Nisa Investment Advisors, L.L.C.	86,545.7	102,555.7	104,755.7	112,555.7	137,170.7	147,170.7	138,735.7	175,835.7
Nli International Incorporated	-	-	-	61,300.0	69,400.0	57,900.0	62,100.0	-
Nomura Asset Management Company Limited	22,122.1	17,320.7	17,320.7	21,220.7	75,750.7	101,734.3	138,834.3	192,222.9
Nomura Asset Management U.S.A. Inc.	-	-	-	-	89,900.0	98,300.0	143,700.0	106,500.0
Nomura Holdings Inc.	284,834.3	581,772.9	757,660.0	856,475.7	907,825.0	1,024,635.0	804,044.3	358,752.9
Norges Bank Investment Management	-	-	-	-	69,137.1	182,890.7	213,890.7	639,774.3
Norris Perne & French LLP/Mi	4,349.3	5,957.1	5,957.1	5,957.1	5,657.1	5,657.1	5,657.1	5,622.9
North American Management Company	4,600.0	2,200.0	2,200.0	2,200.0	2,200.0	2,200.0	2,200.0	39,570.0
North Fork Bank	11,800.0	11,655.0	10,277.9	10,802.9	11,895.0	12,480.0	8,380.0	9,480.0
North Peak LLC	959,400.0	-	-	-	-	-	-	-

**Exhibit-16**

**Shares Held by Institutions During the Class Period**

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
Northeast Investment Management, Inc.	35,350.0	39,240.7	39,640.7	40,655.0	40,297.9	40,297.9	32,447.9	32,495.0
Northern Capital Management LLC	9,075.0	-	-	-	-	-	-	-
Northern Oak Capital Management, Inc.	-	-	-	-	5,645.0	5,645.0	5,145.0	5,145.0
Northern Trust Company of Connecticut	219,129.3	238,549.3	169,649.3	132,849.3	70,749.3	103,349.3	192,949.3	163,267.1
Northern Trust Corporation	6,833,765.0	6,785,697.9	6,693,489.3	6,446,887.1	5,849,782.1	6,219,012.9	6,279,920.7	6,321,617.9
Northrop Grumman Investment Management Company	17,000.0	-	-	-	-	13,000.0	13,000.0	-
Northstar Investment Advisors, L.L.C.	32,200.0	32,200.0	31,200.0	31,200.0	-	-	-	-
Northwestern Mutual Investment Services, Inc.	643,335.0	627,117.1	628,517.1	653,617.1	601,317.1	621,117.1	541,917.1	528,217.1
Northwestern Mutual Life Insurance Co	75,000.0	89,250.0	89,250.0	104,250.0	104,250.0	104,250.0	117,650.0	-
Norwest Bank Minnesota North, N.A.	25,062.1	25,062.1	-	-	-	-	-	-
Norwest Bank Minnesota, N.A.	91,197.9	81,247.1	-	-	-	-	-	-
Norwest Bank South Dakota, National Association	6,720.7	6,720.0	-	-	-	-	-	-
Numeric Investors, LLC	-	9,400.0	-	-	-	-	-	-
NWQ Investment Management Company, LLC	708,652.1	572,107.9	510,980.0	7,477.1	-	-	-	-
Nye (Richard B.)	363,700.0	87,852.9	-	-	-	-	-	-
Nye, Parnell & Emerson Capital Management Inc.	62,955.0	83,244.3	84,480.0	100,360.0	102,212.9	110,135.0	74,712.9	44,390.0
Oak Associates	9,920.7	-	-	-	-	-	-	-
Oakmont Corporation	-	-	3,300.0	-	-	-	-	-
Oam Avatar, LLC	-	-	-	-	-	-	110,055.0	101,962.1
Ocean Fund Advisors LLC	-	-	126,187.1	126,187.1	221,837.1	-	256,650.0	-
Offitbank	8,377.9	8,377.1	3,747.1	3,747.1	4,445.7	3,484.3	4,017.1	4,295.0
Ohio National Life Insurance Co	33,700.0	33,700.0	24,700.0	24,700.0	24,700.0	-	24,700.0	24,400.0
Ohio-Public Employees Retirement System (Pers)	1,702,869.3	1,858,279.3	1,991,230.7	2,005,699.3	2,312,452.9	2,416,517.9	2,784,970.7	3,490,490.0
Ohio-State Teachers Retirement System	2,356,532.1	2,388,282.1	2,444,380.7	2,532,382.1	2,722,347.9	2,859,447.9	2,838,447.9	2,700,947.9
Old Mutual Asset Managers (Uk) Limited	-	-	-	-	7,600.0	21,900.0	31,600.0	-
Old National Trust Company	20,547.9	20,715.7	19,767.1	19,667.1	24,525.0	25,050.0	20,449.3	22,720.7
Omega Advisors Inc.	-	-	-	-	-	381,600.0	-	-
Onyx Capital Management, L.L.C.	35,000.0	-	-	-	-	-	-	-
Oppenheimer Funds, Inc.	7,604,500.0	5,112,037.9	4,538,637.9	3,400,937.9	3,015,802.1	2,280,287.1	2,140,787.1	1,342,569.3
Opus Investment Management, Inc.	113,987.1	112,785.7	111,385.7	105,785.7	100,585.7	83,985.7	78,085.7	78,285.7
Oracle Investment Management, Inc.	450,000.0	-	100,000.0	-	-	-	-	-
Orbimed Advisors LLC.	1,391,000.0	1,385,300.0	1,684,500.0	1,987,500.0	2,270,500.0	2,855,000.0	3,060,600.0	3,980,200.0
Orbitex Management, Inc.	-	-	-	-	-	12,000.0	12,000.0	-
Origin Capital Management LLC	-	-	-	-	-	-	-	200,000.0
Orleans Capital Management	45,200.0	45,300.0	23,800.0	8,900.0	7,400.0	7,400.0	7,400.0	-
Osborne Partners Capital Management	10,420.0	10,420.0	10,420.0	10,420.0	7,720.0	7,520.0	7,520.0	7,520.0
Osterweis Capital Management, Inc.	2,000.0	2,000.0	-	-	-	-	-	-
P. Schoenfeld Asset Management	707,200.0	282,149.3	246,210.7	239,070.7	239,070.7	-	-	-

**Exhibit-16**

**Shares Held by Institutions During the Class Period**

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
PA Commonwealth of Public School Employees Retirement Sy	-	2,029,657.1	1,919,272.9	1,421,590.7	1,664,910.7	1,640,560.7	1,528,060.7	835,529.3
Pacific Assets Management, LLC	19,950.0	7,002.1	-	-	-	-	-	-
Pacific Capital Bancorp/Ca	-	71,342.9	71,042.9	57,542.9	56,920.7	-	57,220.7	49,520.7
Pacific Income Advisers, Inc.	-	48,555.0	51,795.0	-	-	-	-	-
PADCO Advisors Ii, Inc.	-	-	1,255.0	1,455.0	2,475.0	3,285.0	4,685.0	4,935.0
PADCO Advisors, Inc.	-	-	148,027.1	150,230.7	71,632.1	95,600.0	71,790.0	76,175.7
Palisade Capital Management, L.L.C.	12,100.0	14,445.0	12,445.0	9,512.1	-	-	-	15,500.0
Palm Beach Investment Advisers LLC	4,200.0	49,125.0	52,800.0	14,050.0	8,840.0	10,590.0	-	-
Panagora Asset Management, Inc.	406,265.7	539,255.7	513,177.1	615,950.7	728,712.9	750,912.9	755,312.9	749,612.9
Papp (L. Roy) & Associates	850.0	7,750.7	7,750.7	9,179.3	7,219.3	7,219.3	7,219.3	7,219.3
Para Advisors, LLC	-	-	-	-	-	126,094.3	-	212,532.9
Paradigm Asset Management Company, LLC	301,230.7	290,807.1	281,397.9	306,175.0	299,580.7	389,635.0	224,170.7	226,785.7
Parametric Portfolio Associates	-	-	-	-	-	410,757.1	441,662.9	476,189.3
Paramount Biocapital Asset Management, Inc.	22,650.0	-	-	-	-	-	-	-
Park National Corp/Oh	19,967.1	25,327.9	6,812.1	6,547.9	7,820.0	7,270.0	7,167.1	7,467.1
Parker/Hunter, Inc.	4,080.0	4,855.0	4,625.0	4,069.3	-	-	-	-
Parsons Capital Management, Inc.	60,952.9	60,642.9	59,587.9	59,687.9	55,142.9	53,330.7	48,330.7	46,230.7
Parthenon Capital Management, LLC	2,380.0	2,380.0	2,380.0	4,760.0	4,760.0	4,960.0	4,990.0	4,990.0
PASCO Investment Advisors Inc.	-	-	-	-	-	-	-	475.0
Payden & Rygel Investment Group	-	-	-	-	-	-	-	-
Payson (H.M.) & Company	14,674.3	14,249.3	14,149.3	13,934.3	11,734.3	-	-	11,115.7
Peapack Gladstone Financial Corp.	-	-	-	-	9,885.7	9,985.7	10,362.1	9,710.0
Pekin, Singer & Shapiro Asset Mgt, Inc.	-	77,130.0	63,630.0	58,930.0	47,330.0	43,735.0	41,330.0	66,737.1
Penn Mutual Life Insurance Co	-	8,695.7	-	298,660.0	9,319.3	8,830.7	10,060.0	7,750.0
Peoples Mutual Holdings	87,837.9	73,704.3	73,704.3	84,922.9	84,127.9	82,427.9	88,442.9	83,712.9
Pequot Capital Management, Inc.	-	-	-	-	-	-	1,481,300.0	3,466,800.0
Perigee Investment Counsel, Inc.	30,820.7	-	-	-	-	-	-	-
Perry Corporation	873,600.0	-	-	-	-	-	-	-
Perseus, L.L.C.	10,000.0	-	-	-	-	-	-	-
Petersen, Flynn & Dinsmore, Inc.	-	-	-	-	-	10,000.0	31,515.0	80,200.0
Philadelphia Investment Management Company	-	35,960.0	32,250.0	33,100.0	33,060.0	32,990.0	32,250.0	28,365.0
Pilgrim Baxter & Associates Ltd.	17,400.0	123,065.7	-	472,519.3	682,700.0	-	1,723,300.0	512,400.0
Pinnacle Associates, Ltd.	5,985.7	6,292.9	5,837.1	5,837.1	5,030.7	5,132.1	5,810.0	8,422.1
Pinnacle International Management LLC	-	-	-	-	-	-	-	8,722.1
Pinnacle Management And Trust Company	300.0	357.1	357.1	357.1	357.1	357.1	-	40.0
Pioneer Investment Management Inc.	2,050,417.9	2,297,777.9	2,247,782.9	2,262,782.9	1,192,702.9	1,194,535.0	812,580.7	1,497,060.0
Pitcairn Group L.P.	6,130.0	8,027.1	26,877.9	32,550.7	32,232.1	31,555.7	26,547.9	27,077.1
PNC Financial Services Group, Inc.	1,362,450.7	1,312,745.0	1,270,889.3	1,263,072.1	1,251,634.3	1,287,492.9	1,203,725.0	1,217,842.1

**Exhibit-16**

**Shares Held by Institutions During the Class Period**

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
Portola Group, Inc.	-	-	4,222.9	4,104.3	4,104.3	-	-	-
Prescott Group Capital Management, L.L.C.	-	-	-	-	-	-	-	7,140.0
Price (T.Rowe) Associates Inc	10,750,242.1	10,876,507.9	9,135,715.7	7,668,437.9	7,756,717.9	7,403,247.1	3,793,912.1	3,274,340.0
Primecap Management Company	43,336,157.9	41,085,377.1	33,823,082.9	33,015,694.3	30,877,444.3	30,445,507.1	30,405,007.1	31,146,004.3
Principal Financial Group, Inc.	1,524,819.3	2,117,724.3	2,668,775.0	1,664,585.7	1,550,902.9	2,265,197.9	1,359,589.3	1,201,514.3
Private Asset Management, Inc.	85,255.0	85,904.3	83,872.9	81,652.9	147,030.0	64,600.0	58,240.7	50,370.0
Provident Investment Advisors, Inc.	4,100.7	4,000.7	3,850.0	3,510.7	37,857.9	17,137.9	13,277.1	9,152.9
Provident Investment Counsel Inc	-	4,915,550.0	4,634,255.7	5,380,372.1	4,268,497.1	761,727.1	720,927.1	346,727.1
Provident Trust Company	-	-	-	-	-	-	750.0	-
Prudential Equity Group, Inc.	-	299,132.1	306,442.9	377,890.7	75,549.3	472,280.0	709,055.0	765,560.7
Prudential Financial, Inc.	2,554,942.1	3,576,982.9	3,230,837.1	2,656,729.3	2,861,867.1	2,848,500.0	2,802,667.9	2,685,082.1
Prudential PLC	-	-	-	4,495.0	4,495.0	5,100.0	5,100.0	8,500.0
Putnam (FL) Investment Management Company	9,545.0	9,154.3	9,154.3	8,935.0	8,935.0	8,757.9	7,907.9	7,832.9
Putnam Investment Management, LLC	150,910.7	50,982,165.7	55,288,450.0	51,596,604.3	32,137,994.3	30,031,300.0	32,382,975.7	30,374,760.0
Quaker Partners LLC	-	-	-	-	23,100.0	-	8,800.0	-
Qwest Asset Management	556,925.7	595,090.0	564,242.1	518,080.7	493,687.1	493,087.1	457,335.0	408,624.3
Rainier Investment Management	775,880.0	740,375.0	747,590.0	690,027.9	1,012,427.9	871,477.9	719,702.9	-
Rampart Investment Management Company, Inc.	-	-	-	-	-	-	1,050.0	-
Ramsey Quantitativ Systems	-	-	-	-	-	51,900.0	19,500.0	72,600.0
Ray (Gerald L) & Associates	268,717.9	270,815.0	270,815.0	269,377.1	268,950.7	268,050.7	274,025.7	270,325.7
Raymond James Trust Company	7,577.1	9,542.9	11,442.1	11,582.9	12,572.9	12,872.9	12,572.9	7,440.7
RBC Dain Rauscher	16,562.1	133,972.9	158,580.7	33,470.7	151,097.9	106,890.0	59,772.1	59,962.1
RE Advisers Corp.	243,950.0	243,950.0	26,200.0	-	-	-	-	-
Regions Financial Corporation	194,470.7	198,870.7	197,315.7	-	264,874.3	318,434.3	312,029.3	254,512.9
Renaissance Group, LLC	-	-	-	-	-	-	80,950.0	118,675.7
Renaissance Technologies, LLC	-	-	-	306,400.0	411,400.0	758,400.0	936,900.0	1,441,900.0
Renberg Capital Management, Inc.	3,000.0	3,000.0	4,000.0	3,000.0	3,000.0	3,000.0	3,000.0	3,000.0
Retirement Capital Advisors	-	-	-	-	-	175.0	175.0	175.0
Rice, Hall, James & Associates	-	-	3,400.0	3,400.0	-	-	-	-
Richards & Tierney, Inc/II	8,955.7	10,502.9	12,602.9	9,402.9	9,402.9	9,802.9	8,602.9	13,402.9
Riggs Bank N.A./Wa	159,815.7	159,690.7	153,515.7	153,315.7	74,590.7	75,150.7	68,975.7	68,410.7
Righttime Econometrics, Inc.	23,007.9	21,535.7	36,094.3	17,394.3	14,537.1	16,565.7	13,612.1	-
Rittenhouse Trust Company (The)	11,250.0	12,130.7	12,880.0	13,237.1	13,387.1	13,387.1	14,027.9	14,967.9
Riverbridge Partners LLC	-	-	-	8,900.0	9,400.0	8,600.0	9,260.0	8,940.0
Rnc Capital Management LLC	-	-	-	-	-	-	-	8,275.0
Rochdale Investment Management Inc	-	6,167.1	6,132.1	6,332.1	6,489.3	6,574.3	7,495.0	7,547.9
Rockefeller Financial Services, Inc.	55,100.0	373,412.1	373,412.1	427,512.1	389,912.1	344,312.1	42,012.1	11,500.0
Roll And Ross Asset Management Corp.	-	5,600.0	37,700.0	-	-	32,500.0	31,700.0	39,500.0

# Exhibit-16

## Shares Held by Institutions During the Class Period

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
Roosevelt Investment Group Inc.	-	-	-	142,737.1	63,259.3	-	-	-
Rorer Asset Management LLC/Pa	1,558,392.9	-	-	-	-	-	-	-
Rothschild Investment Corporation	71,392.9	70,997.9	71,297.9	69,305.7	67,805.7	69,859.3	64,859.3	61,414.3
Roxbury Capital Management	-	1,545,857.1	4,400,494.3	4,395,284.3	4,470,327.9	4,454,389.3	4,327,309.3	3,958,470.7
Royal Bank of Scotland Group, PLC	293,874.3	28,952.1	16,560.7	83,189.3	82,284.3	75,550.7	69,985.7	61,485.7
Royal London Mutual Insurance Society Limited (The)	78,350.0	79,055.7	100,245.7	110,445.7	229,045.7	-	-	-
Ruane, Cunniff & Goldfarb Inc.	5,200.0	6,187.9	6,187.9	6,187.9	6,387.9	6,387.9	7,532.9	7,594.3
Russell (Frank) Company Inc	433,432.1	-	-	-	2,402,072.9	2,108,964.3	1,373,480.0	1,099,797.9
S & Co., Inc.	2,425.0	38,920.7	2,425.0	-	2,425.0	2,425.0	2,425.0	452,055.0
S&T Bank/Pa	862.1	860.7	-	-	-	-	-	-
S.A.C. Capital Advisors, LLC	-	57,500.0	75,160.0	-	-	-	491,500.0	1,304,500.0
Safeco Corporation	120,487.9	-	-	-	-	-	-	-
Salem Investment Counselors, Inc.	-	6,332.9	7,712.9	7,712.9	7,712.9	7,712.9	-	8,124.3
San Francisco Sentry Investment Group	11,540.0	11,540.0	11,540.0	11,540.0	5,429.3	12,040.0	12,040.0	12,040.0
Santa Barbara Asset Management	-	-	-	-	-	-	10,999.3	7,017.1
Sarofim, Faye	14,935.0	18,377.9	18,377.1	19,655.7	19,655.7	19,155.7	19,155.7	19,580.7
Sass (M.D.) Investors Services, Inc.	-	-	-	8,000.0	-	-	-	-
Satellite Asset Management	3,000,600.0	465,240.7	465,240.7	465,240.7	465,240.7	-	-	-
Schroder Investment Management Group	1,793,164.3	1,974,412.1	789,035.7	711,905.0	708,139.3	698,780.0	1,381,344.3	4,531,339.3
Schulhoff & Company, Inc.	21,670.0	21,670.0	21,670.0	21,670.0	21,670.0	17,990.0	19,490.0	19,490.0
Schupf (H.A.) & Co., Inc.	-	-	-	-	-	-	-	8,000.0
Schwab (Charles) Investment Management, Inc.	1,193,107.9	1,628,345.0	1,730,547.9	1,732,585.0	1,727,810.0	1,780,035.0	1,845,164.3	1,834,489.3
Schwartz Investment Counsel, Inc.	6,400.0	7,984.3	5,967.9	6,182.1	6,182.1	6,182.1	6,682.1	7,682.1
Sears Investment Management Co	159,500.0	80,337.9	55,700.0	34,100.0	-	-	-	-
Seaward Management Corporation	-	-	-	-	-	-	-	89,285.0
Securities Mgmt & Research	-	44,700.0	44,700.0	44,700.0	44,700.0	175,850.0	176,500.0	177,300.0
Security Asset Management	3,915.0	-	5,817.9	-	5,817.9	4,657.9	80,647.9	-
Security Management Company, LLC	190,055.7	376,402.9	479,015.0	276,015.0	314,215.0	255,715.0	387,342.1	416,442.1
Security National Bank of South Dakota	11,240.0	5,500.0	5,500.0	5,500.0	5,500.0	5,500.0	5,500.0	5,500.0
Segall Bryant & Hamill Investment Counsel	14,200.0	13,289.3	12,517.1	12,000.0	12,000.0	11,800.0	11,800.0	11,800.0
Seligman J.W.&Co Incorporated	-	-	648,300.0	648,300.0	14,599.3	1,670.0	1,830.0	116,385.0
Seminole Management Company, Inc.	-	-	-	-	-	300,000.0	-	-
Seneca Capital Advisors LLC	175,000.0	174,930.0	174,930.0	-	-	174,930.0	174,930.0	174,930.0
Seneca Capital Management LLC	150.0	-	302.1	-	170.0	-	-	-
Sentinel Trust Company, Lba	5,300.0	5,300.0	5,300.0	5,300.0	5,300.0	-	-	-
Sentry Investment Management Inc	-	-	-	36,500.0	67,100.0	69,600.0	69,600.0	69,600.0
Sequoia Analytical Investors, LLC	-	-	-	39,940.0	23,800.0	44,160.0	51,570.0	17,930.0
SG Cowen & Company, LLC	101,175.0	172,409.3	176,492.1	148,482.9	128,682.9	86,482.9	96,277.1	96,970.7

**Exhibit-16**

**Shares Held by Institutions During the Class Period**

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
Shaw (George T.)	18,980.7	12,042.9	-	-	-	-	-	-
Shaw D.E. & Co., Inc.	-	-	188,600.0	-	-	-	-	-
Shoreline Investment Management	-	-	155,000.0	155,000.0	80,000.0	-	-	-
Shufro, Rose & Co., LLC	44,770.0	34,185.7	28,824.3	29,024.3	28,299.3	28,732.1	27,574.3	27,259.3
Simmons First Trust Company, N.A.	660.0	860.0	860.0	860.0	860.0	1,287.1	360.0	360.0
Sirach Capital Management, Inc.	-	-	35,000.0	18,000.0	18,000.0	18,000.0	18,000.0	-
SIT Investment Associates Inc	315,600.0	467,600.0	564,200.0	565,700.0	568,700.0	571,750.0	550,250.0	562,750.0
SKBA Capital Management, LLC	-	139,735.0	66,405.7	27,430.0	-	-	-	-
Sloate, Weisman, Murray & Company, Inc.	-	107,385.0	-	-	-	-	-	-
Smith Asset Management Group, L.P.	100.0	150.0	150.0	150.0	-	-	-	-
Smoot, Miller, Cheney & Company	40,380.0	25,350.0	25,200.0	24,400.0	118,300.0	102,650.0	103,800.0	52,000.0
Snyder Capital Management, LP	-	-	-	8,460.0	-	-	-	-
Snyder, Jennifer, C.	-	-	-	-	11,790.0	18,080.0	15,700.0	15,700.0
Soros Fund Management LLC	6,860.0	250,000.0	250,000.0	-	-	-	-	-
Sound Shore Management, Inc.	-	-	-	-	-	-	2,357,300.0	1,468,100.0
Southtrust Asset Management Company	42,577.1	-	-	-	-	-	-	-
Spears (W.G.), Grisanti & Brown, LLC	-	6,750.0	6,750.0	6,750.0	6,750.0	6,850.0	6,850.0	6,850.0
SSI Investment Management Inc.	-	-	-	-	27,850.0	125.0	125.0	-
St Paul Travelers Companies, Inc.	-	-	-	352,510.0	249,680.0	99,820.0	2,780.0	2,780.0
St. Germain (D.J.) Company, Inc.	-	-	-	3,962.1	3,962.1	-	-	-
Standard Life Investments (Usa) Limited	-	-	-	340,127.1	587,910.7	696,119.3	717,632.1	779,942.9
Starbuck, Tisdale & Associates	9,145.7	9,145.7	9,245.7	9,967.9	10,427.9	9,867.9	11,867.9	11,867.9
State Farm Mutual Automobile Insurance Co	1,740,000.0	2,070,600.0	2,070,600.0	2,077,300.0	2,077,300.0	2,077,300.0	2,077,300.0	2,077,300.0
State Street Corporation	16,077,570.7	26,425,730.7	26,964,022.9	28,684,042.9	29,770,454.3	31,053,502.1	31,860,317.9	32,775,235.7
State Street Research & Management Company - Other	8,080,550.0	9,211,405.0	10,316,237.1	8,320,274.3	8,644,460.0	8,507,245.0	8,450,342.1	6,617,025.7
Stein Roe & Farnham Incorporated	386,007.9	342,474.3	338,355.7	335,135.0	33,535.0	-	72,100.0	406,400.0
Steinberg Global Asset Management, Ltd.	9,710.0	10,520.7	10,680.0	11,830.0	11,882.1	10,582.1	10,382.1	9,035.0
Steinroe Investment Counsel, LLC	-	-	-	-	239,289.3	227,319.3	207,055.0	166,485.0
Stephens Inc.	-	-	-	-	-	-	-	100.0
Sterne Agee & Leach Group, Inc.	15,925.0	1,037.9	6,209.3	4,899.3	-	-	-	-
Stevenson Capital Management	4,629.3	4,937.9	4,937.9	-	4,500.0	4,500.0	3,000.0	3,000.0
Stichting PensioEnfonds Abp	-	-	-	-	-	359,897.1	519,497.1	1,125,005.0
Stock Yards Bank And Trust Company	-	-	-	-	-	-	-	-
Stonebridge Capital Management Inc	-	-	6,490.0	16,640.0	25,290.0	28,690.0	30,090.0	15,700.0
Stoneridge Investment Partners, L.L.C.	151,620.0	203,980.0	187,025.0	-	125,785.0	127,310.0	109,970.0	109,620.0
Storie Advisors, LLC	-	-	-	-	-	10,000.0	-	-
Stratton Management Company	25,174.3	22,865.7	20,787.9	20,487.9	18,304.3	17,304.3	16,685.0	17,085.0
Strong Capital Management, Inc.	114,475.0	217,055.7	1,213,355.7	2,385,597.9	1,179,637.1	402,797.9	94,017.1	413,139.3



**Exhibit-16**

**Shares Held by Institutions During the Class Period**

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
Sturdivant & Company, Inc.	-	-	44,172.1	44,772.1	44,772.1	-	24,600.0	-
Suffolk Capital Management Inc.	637,720.7	-	-	-	-	-	-	-
Sumitomo Life Insurance Company	-	-	178,240.0	260,620.0	217,330.7	138,567.9	123,080.7	129,732.1
Summit Investment Partners, Inc.	81,569.3	61,195.0	47,634.3	31,460.7	32,014.3	32,879.3	31,419.3	31,419.3
Sun Life Assurance Company of Canada	150,900.0	97,595.7	11,317,602.9	84,122.9	17,427.9	64,092.9	125,492.9	95,125.7
Sunrise Partners Limited Partnership	641,600.0	8,835.0	-	31,447.9	85,112.9	228,112.9	273,412.9	109,967.9
Suntrust Banks, Inc.	1,226,562.1	1,548,759.3	1,516,654.3	1,321,917.1	1,425,119.3	1,421,295.0	1,459,579.3	1,337,562.1
Susquehanna Trust & Investment Company	-	-	-	-	-	5,240.0	-	-
Swan (Philip) V. Associates Inc.	9,440.0	20,724.3	26,974.3	27,974.3	28,674.3	30,299.3	30,674.3	37,119.3
Swarthmore Group (The)	-	-	-	169,177.9	212,075.0	212,075.0	212,075.0	220,825.0
Swiss Re Asset Management Americas, Inc.	110,000.0	115,400.0	120,000.0	110,000.0	-	96,800.0	-	135,000.0
Synovus Financial Corporation	283,045.0	158,064.3	322,169.3	221,309.3	93,812.9	164,562.1	16,049.3	39,325.0
Systematic Financial Management, L.P.	414,019.3	103,325.0	104,610.7	106,350.0	52,935.7	34,767.1	35,295.7	33,920.0
T/F Partners	60,800.0	-	-	-	-	-	-	-
Taconic Capital Advisors, L.L.C.	188,000.0	187,900.7	187,900.7	187,900.7	180,400.7	187,900.7	-	-
Talon Asset Management	-	4,500.0	4,500.0	4,500.0	4,500.0	4,500.0	-	91,900.7
Taunus Corporation	16,143,675.0	12,955,765.0	11,471,090.7	13,775,037.9	13,703,444.3	14,713,319.3	17,611,267.9	22,148,915.0
Tcw Group, Inc. (The)	337,580.7	363,517.9	468,242.9	710,105.0	780,802.1	827,505.7	1,470,270.0	867,365.0
Td Asset Management, Inc	381,387.9	395.0	-	957,475.0	911,482.9	766,582.9	619,472.1	696,145.7
Teachers Advisors, Inc.	179,950.0	205,345.0	255,045.0	281,145.0	464,010.0	518,380.7	681,320.0	889,220.0
Terre Haute First National Bank	1,690.0	1,690.0	1,490.0	1,390.0	1,390.0	1,390.0	1,390.0	1,390.0
Tewksbury Capital Management Ltd	-	-	-	5,400.0	-	-	-	-
Texas - Teacher Retirement System	3,889,787.1	3,792,787.1	3,866,227.1	3,866,227.1	4,031,227.1	4,000,227.1	4,142,227.1	4,047,000.0
Thales Fund Management, L.L.C.	-	237,600.0	-	-	-	-	-	256,000.0
Third Point Management Company LLC	68,369.3	90,000.0	-	-	-	-	-	-
Thomas White International Ltd	-	-	-	-	-	-	-	16,684.3
Thompson, Siegel & Walmsley, Inc.	53,247.9	50,040.7	53,410.7	48,725.7	48,769.3	46,179.3	47,675.0	38,249.3
Thompson/Rubinstein Investment Management, Inc.	-	-	-	-	7,800.0	-	-	-
Thornburg Investment Management Inc.	33,320.0	50,760.0	70,760.0	121,474.3	108,405.0	71,995.0	-	-
Thrivent Financial For Lutherans	613,582.1	928,832.1	1,049,502.1	1,373,982.1	1,052,840.7	1,419,092.1	1,791,852.9	1,920,052.9
Thrivent Investment Management Inc	134,915.0	144,814.3	149,514.3	152,914.3	155,614.3	156,214.3	153,314.3	154,714.3
TIAA-CREF Trust Company FSB/MO	15,700.0	16,182.1	16,955.0	21,670.7	21,270.0	23,307.1	60,699.3	64,172.1
TIAA-CREF Investment Management, LLC	8,306,357.1	9,596,255.0	9,500,555.0	9,666,755.0	12,229,045.0	12,820,459.3	14,708,652.9	16,921,652.9
Times Square Capital Management	-	-	-	579,049.3	564,449.3	562,949.3	557,049.3	552,449.3
Tobias, Seth	35,000.0	-	-	-	20,000.0	20,000.0	-	-
Todd Investment Advisors Inc	10,300.0	10,000.0	9,800.0	9,800.0	9,800.0	9,800.0	-	-
Tompkins Trustco Inc	15,550.7	15,944.3	11,802.9	11,802.9	11,927.9	12,102.9	12,147.9	11,827.9
Tower Asset Management LLC	-	-	46,470.7	103,377.1	50,410.0	48,027.1	42,862.9	63,062.1

**Exhibit-16**

**Shares Held by Institutions During the Class Period**

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
Tradition Capital Management LLC	-	-	-	-	-	-	35,475.7	58,425.7
Train, Babcock Advisors LLC	40,485.0	118,644.3	115,607.1	113,357.1	113,107.9	108,514.3	111,665.7	75,080.7
Trainer, Wortham & Company	5,160.0	8,900.0	104,442.9	96,270.0	64,735.7	64,007.9	63,857.9	63,507.9
Transamerica Investment Management LLC	-	39,844.3	44,190.7	40,790.7	41,912.1	40,412.1	42,412.1	2,361,987.9
Trees Front Associates Inc	-	-	5,825.0	6,039.3	5,100.0	4,745.0	-	12,195.0
Trellus Management Company, LLC	-	-	-	-	-	40,000.0	-	66,000.0
Trilogy Advisors, LLC	-	-	-	-	-	-	-	1,046,307.1
Trinity Investment Management Corporation	13,565.7	620,482.1	574,882.1	575,582.1	532,044.3	299,117.9	229,517.9	135,717.9
Trust & Fiduciary Management Services Inc	-	-	-	-	-	2,260.0	2,260.0	2,260.0
Trust Company of Oklahoma (Tulsa)	-	8,932.1	7,052.1	6,945.0	6,045.0	6,825.0	11,825.0	-
Trust Company of Toledo, N.A.	21,700.0	5,555.0	5,555.0	5,555.0	-	-	-	-
Trust Company of Vermont	-	-	-	-	-	-	-	310.0
Trust Company of Virginia	-	-	-	-	-	5,100.0	8,550.0	19,815.0
Trustmark National Bank, Trust Department	-	5,912.1	8,142.1	7,792.1	8,067.1	8,067.1	5,552.1	5,522.1
Tudor Investment Corporation	-	-	-	-	-	151,300.0	-	-
Turner Investment Partners, Inc.	323,970.0	450,332.9	770,267.1	1,900.0	-	-	-	-
Tweedy Browne Company, L.L.C.	5,858,905.7	5,687,914.3	5,660,507.1	5,564,887.9	5,696,064.3	5,696,110.7	5,768,099.3	5,782,095.7
Twin Capital Management, Inc.	-	75,650.0	10,300.0	-	-	35,110.0	110,820.0	38,920.0
U.S. Bancorp (Minnesota)	3,198,887.1	4,466,420.7	4,899,492.1	4,827,729.3	4,586,064.3	4,604,490.7	4,776,794.3	5,336,732.9
U.S. Global Investors, Inc.	4,500.0	5,070.0	5,070.0	35,070.0	5,070.0	20,070.0	15,000.0	13,000.0
UBS Ag, New York Branch	137,439.3	-	-	-	-	-	-	-
UBS Americas Inc.	865,832.1	2,328,999.3	3,505,882.1	2,148,240.7	2,305,137.9	2,933,917.9	2,772,977.9	2,389,084.3
UBS Global Asset Management (Americas) Inc	914,660.0	884,199.3	1,326,199.3	1,364,152.1	724,552.1	732,952.1	230,452.1	124,785.0
UBS Global Asset Management (Uk) Limited	217,165.7	125,212.1	128,112.1	132,462.1	137,989.3	253,389.3	245,237.1	228,260.7
UBS O'Connor LLC	-	-	-	-	64,800.0	55,000.0	332,400.0	246,000.0
UBS Securities LLC	285,230.0	884,719.3	1,695,864.3	1,028,855.7	1,835,467.1	1,746,335.0	2,533,630.7	1,773,650.0
Ullman (John G.) & Associates, Inc.	94,149.3	42,987.9	38,164.3	37,482.9	37,195.0	36,415.0	41,165.0	52,607.9
UMB Bank N/A/MO	374,629.3	366,694.3	375,534.3	367,050.7	310,702.9	290,492.1	287,507.9	274,527.1
Union Planters Bank, N.A.	190,250.7	183,374.3	218,377.1	221,674.3	225,582.1	231,905.0	231,095.7	224,720.7
Unionbancal Corp	537,005.0	536,990.0	493,057.9	426,350.0	418,365.0	432,475.7	457,865.7	482,115.0
United National Bank/WV	33,714.3	28,679.3	26,142.9	24,450.7	24,510.7	-	-	22,009.3
United States Trust Company of New York	1,194,847.9	1,427,135.0	1,408,852.1	1,373,072.9	1,665,922.9	1,735,099.3	1,768,302.1	1,447,615.0
United Trust Bank/NJ	11,900.0	10,700.0	26,150.0	44,787.9	48,534.3	39,887.9	14,887.9	10,587.9
Unizan Financial Services Group N.A.	35,467.1	33,967.1	31,967.1	26,145.7	22,520.0	20,820.0	20,820.0	57,927.9
Ursus Capital Management, L.L.C.	-	-	-	-	-	-	-	20,000.0
USAA Investment Management Company	1,363,300.0	1,535,962.1	1,492,855.0	1,388,420.7	1,216,897.9	1,165,432.9	1,975,590.0	2,310,190.0
Vanguard Group, Inc. (The)	16,847,205.7	18,124,782.1	18,632,344.3	20,475,549.3	20,672,757.1	20,966,890.7	20,941,509.3	22,362,729.3
Vantage Global Advisors, Inc.	118,162.1	9,089.3	9,089.3	232.9	-	-	-	-



**Exhibit-16**

**Shares Held by Institutions During the Class Period**

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
Vaughan Nelson Investment Management, L.P.	41,704.3	24,885.0	24,885.0	13,585.0	13,585.0	30,247.1	43,547.1	60,547.1
Vaughan, David Investments, Inc.	141,305.0	149,372.9	147,762.1	146,485.0	146,749.3	152,247.1	154,750.7	157,545.7
Vector Capital Management	-	-	-	900.0	-	32,300.0	49,400.0	12,700.0
Verizon Investment Management Corp	202,312.1	512,642.1	410,307.9	421,880.7	839,022.9	848,122.9	875,622.9	858,377.9
Vestor Capital Corp	-	-	-	-	-	-	102,380.0	103,955.0
Virginia Investment Counselors, Inc.	31,752.9	32,115.0	31,885.7	32,040.7	31,897.1	31,162.1	31,162.1	30,187.1
Virginia Retirement System	387,925.0	281,024.3	281,224.3	280,324.3	353,524.3	340,355.0	345,155.0	370,755.0
Voyageur Asset Management Inc	-	-	8,115.0	8,115.0	8,115.0	8,115.0	8,415.0	8,115.0
Voyageur Asset Management/MA	121,045.0	120,117.1	145,262.9	18,502.9	87,307.1	175,302.1	176,252.1	78,239.3
Wachovia Bank N.A./VA	599,377.1	609,085.0	589,940.7	572,822.9	563,524.3	559,105.7	553,954.3	550,152.9
Wachovia Corp New	4,877,725.0	7,650.0	5,150,360.7	-	4,755,315.0	2,666,525.0	5,488,707.1	5,363,777.1
Waddell & Reed Financial Inc.	4,366,315.0	8,244,920.0	6,875,937.1	4,291,577.1	5,347,832.9	5,560,287.9	7,647,460.7	7,423,190.7
Wade, G W Inc.	-	-	-	1,074.3	200.0	-	-	-
Walnut Asset Management LLC	-	-	-	-	22,412.1	22,412.1	21,140.0	20,047.1
Washington Capital Management, Inc.	60,570.7	29,675.0	24,400.0	-	-	-	-	-
Washington Trust Bank Trust & Inv. Services Division	3,970.0	-	-	-	-	-	-	5,472.9
Washington Trust Company	43,980.0	40,625.0	41,072.9	40,672.9	40,072.9	47,550.0	47,500.0	49,637.1
Waters, Parkerson & Company	-	-	-	7,710.0	7,782.1	5,392.1	5,582.1	5,857.1
WB Capital Management, Inc.	-	5,119.3	-	-	-	7,624.3	7,739.3	7,589.3
WCM Investment Management	93,890.7	-	-	-	-	-	-	-
Webster Bank NA	-	-	-	-	-	-	15,487.1	14,834.3
Wedgewood Investors, Inc.	-	-	-	-	4,500.0	6,700.0	6,600.0	12,200.0
Wedgewood Partners, Inc.	-	-	-	-	-	-	66,925.0	71,125.0
Weintraub Capital Management LLC	-	-	-	-	-	-	-	175,000.0
Weisberg & Fields, Inc.	25,100.0	24,100.0	24,100.0	24,100.0	22,219.3	22,219.3	22,219.3	19,999.3
Weiss, Peck & Greer LLC	91,500.0	586,190.7	580,037.1	495,550.7	529,139.3	191,192.9	46,467.9	29,097.9
Welch & Forbes, LLC	185,867.9	205,960.0	176,439.3	227,462.1	240,412.1	212,097.1	133,570.0	133,902.1
Welch Capital Partners, LLC	15,700.0	15,700.0	15,700.0	15,700.0	15,700.0	94,800.0	288,720.0	372,690.0
Wellington Management Company, LLP	64,739,892.9	427,804.3	515,944.3	534,644.3	485,044.3	67,811,305.0	76,437,819.3	88,859,857.9
Wellington, H.G. & Co., Inc.	-	4,260.7	4,292.1	4,292.1	19,090.7	9,290.0	-	-
Wells Capital Management Inc.	4,732.1	4,845.0	121,070.7	75,300.0	284,555.7	-	-	-
Wells Fargo & Company	26,415.0	18,015.0	3,705,455.0	2,753,345.7	2,990,910.7	3,397,589.3	3,032,649.3	3,708,842.1
Wells Fargo Bank Arizona, N.A.	17,869.3	16,410.0	13,985.0	9,960.0	5,700.0	-	-	-
Wells Fargo Bank Indiana, N.A.	67,250.7	67,050.7	61,382.1	61,127.1	57,827.1	-	-	-
Wells Fargo Bank Iowa, N.A.	-	62,302.9	53,800.7	49,192.1	49,047.1	-	-	-
Wells Fargo Bank Minnesota, N.A.	116,260.0	106,309.3	154,065.7	120,274.3	146,529.3	-	-	-
Wells Fargo Bank Montana, N.A.	39,190.7	38,329.3	37,219.3	36,609.3	36,174.3	-	-	-
Wells Fargo Bank N A	1,785,485.7	2,996,409.3	2,925,082.1	2,125,594.3	2,192,479.3	-	-	-

**Exhibit-16**

**Shares Held by Institutions During the Class Period**

Institution Name	As of the Quarter Ended							
	3/31/2000	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001	9/30/2001	12/31/2001
Wells Fargo Bank Nebraska, N.A.	5,240.0	7,240.0	6,940.0	6,940.0	6,100.0	-	-	-
Wells Fargo Bank New Mexico, NA	-	1,532.9	-	-	-	-	-	-
Wells Fargo Bank South Dakota, National Association	6,720.7	6,720.0	5,457.9	5,385.0	5,385.0	-	-	-
Wells Fargo Bank Texas, N.A.	24,065.7	109,024.3	100,039.3	32,195.0	31,050.0	-	-	-
Wells Fargo Bank West, N.A.	31,032.9	28,499.3	27,714.3	21,464.3	15,014.3	-	-	-
Wells Fargo Bank Wisconsin, N.A.	6,235.0	5,385.0	2,570.0	2,570.0	2,287.1	-	-	-
Wells Fargo Bank Wyoming, N.A.	-	-	-	15,100.0	-	-	-	-
Wells Fargo Investments, LLC	22,884.3	22,812.1	-	27,119.3	27,060.7	37,139.3	-	-
Wendell (David) Associates, Inc.	-	-	6,842.1	8,652.1	8,652.1	8,652.1	8,652.1	8,352.1
Wentworth, Hauser And Violich	28,955.0	27,175.0	23,820.0	24,645.0	24,450.0	339,477.9	608,510.0	827,282.1
Wesbanco Bank Inc.	23,150.0	25,810.7	26,355.0	26,145.0	26,175.7	24,475.7	23,647.9	23,647.9
West Ellis Investment Management Inc.	11,782.9	11,550.0	11,550.0	11,520.0	11,360.0	11,360.0	11,450.0	11,432.1
Western National Trust Company	16,059.3	15,559.3	15,999.3	15,999.3	46,785.0	52,929.3	60,687.1	48,690.0
Westfield Capital Management Company	15,120.0	15,120.0	15,120.0	14,945.0	14,945.0	14,945.0	14,945.0	14,945.0
Weston Asset Management, Inc/Az	-	-	-	21,500.0	20,900.0	21,400.0	20,900.0	14,300.0
Westpeak Global Advisors, L.P.	169,690.0	255,395.0	330,369.3	405,969.3	486,169.3	147,170.7	200,789.3	356,189.3
Westport Asset Management Inc.	9,800.0	9,520.0	9,520.0	9,520.0	9,520.0	9,520.0	9,520.0	9,520.0
Westridge Capital Management, Inc.	-	7,765.0	7,765.0	7,765.0	-	-	-	-
Westwood Management Corp.,(Dallas, Texas)	933,260.7	1,112,502.1	1,018,250.7	-	-	1,367,049.3	1,390,417.1	5,920.7
Whelan And Gratny Capital Management	16,000.0	16,000.0	16,000.0	16,000.0	16,000.0	16,000.0	16,000.0	-
White Oak Capital Management, Inc.	-	-	-	-	5,327.1	5,327.1	5,327.1	5,327.1
White Pine Capital, LLC	-	-	-	5,257.1	5,257.1	4,457.1	-	-
White River Global Fund Management, Inc.	-	-	-	-	-	-	-	-
Whitman, M.J. Advisors Inc./NY	-	-	-	-	32.1	-	-	-
Whitney, Thomas H.P. Jr.	-	50,982.9	51,182.9	48,722.9	49,122.9	49,122.9	49,122.9	47,522.9
Wilbanks, Smith & Thomas Asset Management, Inc.	47,635.7	83,107.1	219,577.9	238,815.7	263,675.7	273,504.3	276,820.7	282,604.3
Williams, Jones & Associates, Inc.	20,335.0	23,440.0	23,640.0	24,457.1	25,760.0	26,585.0	24,925.0	24,425.0
Wilmington Trust Company	343,337.1	128,905.0	113,075.7	81,322.9	73,507.1	70,030.7	75,899.3	76,742.1
Wilmington Trust FSB	7,340.0	10,234.3	12,365.0	12,732.1	17,670.7	17,715.0	20,084.3	33,794.3
Wilson/Bennett Capital Management	-	400.0	400.0	400.0	400.0	745.0	745.0	745.0
Windham Capital Management	63,040.0	-	-	-	-	-	-	-
Winslow Capital Management	-	106,830.0	111,430.0	-	67,550.0	35,700.0	-	-
Wisconsin (State of) Investment Board	593,310.7	602,900.0	109,500.0	127,400.0	160,600.0	224,600.0	224,600.0	222,700.0
Wisconsin Capital Management	12,860.0	13,895.7	13,895.7	14,395.7	14,395.7	18,745.7	18,879.3	17,414.3
Woodford Capital Management, L.L.C.	18,800.0	-	-	3,300.0	-	61,650.0	-	-
Woodmont Investment Counsel	-	-	-	3,819.3	-	-	-	-
Woodstock Corporation	26,517.1	26,557.9	26,557.9	26,740.0	26,740.0	26,740.0	26,740.0	19,062.1
Wright Investors' Service	4,124.3	-	3,420.7	3,420.7	4,420.7	2,920.7	2,920.7	8,097.1

# EXHIBIT 7

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

ALASKA ELECTRICAL PENSION  
FUND, *et al.*, On Behalf of Themselves  
and All Others Similarly Situated,

Plaintiffs,

vs.

PHARMACIA CORPORATION, *et al.*,

Defendants.

Civil Action No. 3:09-1519 (AET)  
(Consolidated)

CLASS ACTION

REBUTTAL REPORT OF  
STEVEN P. FEINSTEIN, PH.D., CFA  
JULY 15, 2011

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### **SCOPE OF PROJECT AND REPORT**

1. In my expert report dated 6 June 2011 (“Feinstein June Report” or “June Report”), I determined that Pharmacia stock traded in an efficient market over the course of the Class Period. I also determined that alleged misrepresentations and omissions caused the price of Pharmacia stock to be artificially inflated over the course of the Class Period. Corrective disclosures caused the inflation to dissipate, the stock price to fall, and investors to suffer losses of up to \$5.92 per share. I determined that aggregate damages estimated by a two-trader proportional trading model using a 90-day bounce-back period that commences on 8 February 2001 amount to \$1.38 billion, or \$1.59 billion assuming the 90-day bounce-back period begins 5 August 2001. Both estimates exclude prejudgment interest.
2. Subsequently, I was asked by Robbins Geller Rudman & Dowd LLP, counsel for the Plaintiffs, to consider and evaluate the arguments and conclusions in the Expert Report of Dr. Kenneth M. Lehn (“Lehn Report”) and the Expert Report of Dr. Anthony Fiorino (“Fiorino Report”) submitted by the Defendants in this matter. This report presents my analysis, findings, and conclusions relating to those two reports.
3. The documents I have reviewed and relied upon in the course of this engagement in addition to those cited in my previous report are listed in Exhibit-1. My credentials and compensation are presented in my June Report, as are prior testimonies provided as of the date of that report. Testimony I have provided since the submission of my first report is identified in Exhibit-2.

### **CONCLUSIONS**

4. Neither the Lehn Report nor the Fiorino Report provide a basis for revising my conclusions of market efficiency, loss causation, and estimated aggregate damages.
5. Dr. Lehn errs in a number of important respects, rendering his analysis unreliable.
6. Dr. Fiorino’s conclusions are based principally on conjecture and are unsupported by the generally accepted methodologies that are widely used to analyze stock return attribution and loss causation.

**DR. LEHN SEES NO SCIENTIFIC BASIS**

7. Dr. Lehn states that he observed no scientific basis indicating that the alleged misrepresentations and omissions about the CLASS data inflated Pharmacia's stock price.

“Based on my review of information that was in the public domain and event study analyses of Pharmacia's stock price that I conducted, it is my opinion that there is no scientific basis to conclude that the alleged misrepresentations in this matter were material. Therefore, there is no scientific basis to conclude that the alleged misrepresentations caused Pharmacia's stock price to be artificially inflated during the class period.”  
**Lehn Report, paragraph 9.**

8. As discussed in my June Report, proper analysis proves the misrepresentations and omissions were material and caused Pharmacia's stock price to be inflated over the course of the Class Period, and that corrective disclosures caused the inflation to dissipate, thereby causing investor losses. Dr. Lehn's numerous methodological errors, oversights of important facts, and misconceptions about fundamental financial principles obscured his view of this scientific evidence.

**A STOCK PRICE NEED NOT RISE ON AN INFLATIONARY  
MISREPRESENTATION DATE**

9. Dr. Lehn asserts that Pharmacia's non-significant stock returns on certain misrepresentation dates are “inconsistent” with Plaintiffs' allegations that the misrepresentations inflated the Pharmacia stock price, and therefore indicate that the alleged misrepresentations and omissions did not cause the Pharmacia stock price to be artificially inflated.

“The event study analysis finds that Pharmacia's residual return on April 17, 2000 is *negative* 0.43% and not statistically significant. This result is inconsistent with the plaintiffs' allegation that the April 15-17, 2000 announcements artificially inflated Pharmacia's stock price.”  
**Lehn Report, paragraph 49 (emphasis in original).**

“The event study analysis shows that Pharmacia's residual return on April 25, 2000 was *negative* 8.05% and statistically significant, which is inconsistent with Plaintiffs' claim that the alleged false statements made



during the analyst conference call artificially inflated Pharmacia's stock price."

*Ibid.*, paragraph 62 (emphasis in original).

10. Dr. Lehn, however, is wrong. Material misrepresentations need not cause a statistically significant stock price rise, because misrepresentations may introduce artificial inflation by preventing a security price from falling rather than by causing the price to increase. The absence of a statistically significant stock price increase is therefore not inconsistent with there having been a new material misrepresentation or omission.
11. A review of the analyst commentary around the time the CLASS study results were released in April 2000 indicates that the market expected the CLASS study to demonstrate Celebrex's GI safety:

"The imminent completion of the CLASS study, conducted to demonstrate a reduction in the incidence of severe GI side effects of ulcers and bleeds, should result in a supplemental filing to remove the NSAID class warning from the label. This should prove to be the single most important event driving the expansion of the COX-2 inhibitors to a dominant position in arthritis treatment."

**"Creation of New 'Porsche Pharma' Offers Potential to Be Better Than Biotech,"** by Richard Stover, Arnhold and S. Bleichroeder, Pharmacia analyst report, 22 March 2000, p. 16.

"The next big thing in the Celebrex story should take place around midyear, when the companies are expected to submit a supplemental NDA (sNDA) with the results of their outcomes trial (the CLASS trial)."

**"Initiating Coverage With an Outperform Rating,"** by Jami Rubin, *et al.*, Morgan Stanley Dean Witter, Pharmacia analyst report, 4 April 2000, p. 5.

"Nevertheless, we would expect COX-2 sales to accelerate after the release of the [CLASS and VIGOR] data, which could occur at DDW in May 2000."

**"MRK's: VIOXX GI Outcomes Data – Details Part 1,"** by Christina Heuer and Mark Striker, Salomon Smith Barney, Merck analyst report, 28 March 2000, p. 3.

12. Given the market's expectation that the CLASS study would show Celebrex's superior GI safety profile relative to NSAIDs, truthful contradictory data would have caused a price decline, but confirmatory data would reasonably maintain the prior price level. The spread between the maintained price level and the lower level the price would have fallen to with

correct information is the artificial inflation introduced by the alleged misrepresentations and omissions.

**Nonetheless, Dr. Lehn's Event Study Indicates a Significant Stock Price Increase Following the Announcement of CLASS Results in April 2000**

13. Dr. Lehn contends the Pharmacia stock price did not rise significantly in reaction to the initial announcement about CLASS results on 17 April 2000. However, he only reports event study results for that one day, and does not consider that the complex information reported may have taken multiple days to be fully understood by the market and incorporated into the stock price.
14. According to the results of Dr. Lehn's own event study, as presented in Exhibit 4 of his report, the Pharmacia residual return on 19 April 2000 was positive and highly statistically significant. The three-day cumulative return on Pharmacia stock from 17 April to 19 April 2000 was also positive, large, and statistically significant.
15. The returns in Dr. Lehn's event study are not logarithmic returns, but rather are percent price changes. In order to compute cumulative returns, estimate the standard deviation of cumulative returns, and determine whether or not the three-day return on 17-19 April 2000 was statistically significant, it was necessary to replicate Dr. Lehn's regression analysis using logarithmic returns. For this exercise, I used the same market and peer group data that Dr. Lehn used, the same dummy variables, and the same estimation period. The results of this regression estimation are presented in Exhibit-3, and the corresponding event study results are presented in Exhibit-4.
16. As shown in Exhibit-4, the three-day cumulative return was 11.75%. The cumulative residual return was 8.92%, which corresponds to a *t*-statistic value of 2.67. This cumulative three-day residual price rise following the initial announcement of the CLASS results on 17 April 2000 was statistically significant at the 0.4% significance level, equivalent to a 99.60% confidence level, when computed using the same one-tailed test approach that Dr. Lehn uses in his event study (p-value equals 0.004). Using a two-tailed test, the price rise is significant at the 0.79% significance level, corresponding to a 0.0079 p-value and 99.21% confidence level.

17. No other information that emerged over the 17-19 April 2000 timeframe, aside from the reported CLASS results, explains the large significant stock price increase. Had Dr. Lehn appropriately widened the event study window, he would have observed this statistically significant stock price increase that followed the allegedly misleading initial CLASS results announcement.

**DR. LEHN'S EVENT STUDY IS FLAWED**  
**AND HIS CONCLUSION ABOUT 7 FEBRUARY 2001 IS WRONG**

18. Among the scientific bases that Dr. Lehn fails to observe for the conclusion that the misrepresentations and omissions caused investor losses is the statistical significance of the Pharmacia stock price decline that occurred on 7 February 2001 as the market disseminated and processed the corrective disclosure about the CLASS data.
19. As noted in my June Report, the Pharmacia stock price declined 2.67% on 7 February 2001. Appropriately accounting for the market effect and the pharmaceuticals sector, and factoring out the New Monsanto chemicals and agricultural business, the residual return on the Pharmacia Pharmaceuticals Stock Price was -4.17% that day. This is an unusually large one-day residual decline. With a *t*-statistic of -2.16, this residual return is statistically significant at the 3.1% significance level (p-value equals 0.031, confidence level is 96.9%).
20. Dr. Lehn fails to observe the statistical significance of the decline in Pharmacia value on 7 February 2001.

“Pharmacia’s residual return on February 7, 2001 was negative 2.90% and not statistically significant.”  
**Lehn Report, paragraph 79.**

21. Dr. Lehn’s incorrect event study finding is the result of the numerous flaws in his event study, as detailed next.

**Dr. Lehn Fails to Control for the Chemical Sector Effect**

22. Dr. Lehn acknowledges that controlling for sector effects is important in the execution of an event study.

“To perform event study analyses in this matter, I examined the relation between Pharmacia’s stock returns and the stock returns of general market indices and Pharmacia’s industry peers.”

**Lehn Report, paragraph 44.**

23. However, the peer companies Dr. Lehn includes in his peer group index are exclusively pharmaceutical companies.

“The Competitor Index is an equal-weighted index comprised of Bristol-Myers Squibb Co., Eli Lilly & Co., Schering-Plough Corp., AstraZeneca plc, GlaxoSmithKline plc, Abbott Laboratories, Novartis AG, American Home Products Corp. and Johnson & Johnson.”

**Lehn Report, paragraph 45, footnote 15.**

24. Dr. Lehn neglects to consider that over the course of the Class Period, Pharmacia’s businesses included not only the pharmaceutical business, but also a chemical and agricultural business. The Company noted that its peers include both pharmaceutical companies and chemical industry companies:

“Because Pharmacia continues in the pharmaceutical business and, through its ownership in new Monsanto, the agricultural business, and since Pharmacia stock has only been publicly traded since April 3, 2000, Pharmacia has continued to use the former Monsanto peer group. This peer group index includes AstraZeneca plc, Aventis, Bayer AG ADR, Dow Chemical Company, E.I. DuPont de Nemours and Company, and Novartis AG.”

**Pharmacia Corporation – Form DEF 14A, filed 13 March 2001, p. 13.**

25. Dr. Lehn makes no effort to control for the effect of the chemical business on the Pharmacia stock price. He omits from his peer group Dow Chemical and DuPont, both of which Pharmacia cited as peers. His failure to appropriately account for peer effects reduces the power of Dr. Lehn’s statistical tests to detect statistically significant price movements.
26. Dr. Lehn could have focused the event study more precisely on the pharmaceuticals portion of Pharmacia’s business. He could have eliminated the chemical sector effect and the effect of any information related to the chemical and agricultural business by factoring out from Pharmacia’s stock price the value of the New Monsanto business, as I did. But, he did not. Nor did he control for the chemical sector effect by including an appropriate

sector index in his event study regression. These deficiencies weaken his tests and distort his entire analysis, rendering his conclusions invalid.

### **Dr. Lehn's Anomalous Choice of Peers and Index Construction Methodology**

27. Another anomaly in the design of Dr. Lehn's event study, which renders his statistical results highly questionable, is the inconsistency between the construction of his selected market index and the construction of his pharmaceuticals peer index. The NYSE market index, which Dr. Lehn used, is a value-weighted index. However, Dr. Lehn built his pharmaceuticals index as an equal-weighted index.<sup>1</sup> Dr. Lehn offers no explanation for this inconsistency.
28. Additionally, Dr. Lehn provides no explanation for how he chose the companies to include in his pharmaceuticals peer group index. His index is neither as comprehensive as the Dow Jones U.S. Pharmaceutical Index, which I used as the basis for my peer index, nor does it even include the same pharmaceutical companies Pharmacia identified as its peers in its Proxy statement.

### **Despite Its Flaws, Dr. Lehn's Event Study Detects an Unusually Large Stock Price Decline on 7 February 2001**

29. Notwithstanding the errors in his event study methodology, Dr. Lehn finds the residual stock price decline that occurred on 7 February 2001 to be severe and unusual. The  $t$ -statistic Dr. Lehn's test associates with the Pharmacia residual stock return on 7 February 2001 is -1.50. A Pharmacia stock price decline of this magnitude, with such an extreme negative  $t$ -statistic, is relatively rare. The probability that a randomly selected residual stock price decline would be of the magnitude observed, or greater, is only 6.75% (p-value equals 0.0675).<sup>2</sup> The residual decline, as Dr. Lehn measures it, would be among the top 6.75% worst residual declines experienced by Pharmacia stock. The rarity of declines this severe reasonably indicates that the observed 7 February 2001 stock price decline was not the result of random volatility, but rather was likely caused by Company-specific information concerning CLASS.

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<sup>1</sup> Lehn Report, paragraph 45, footnote 15.

<sup>2</sup> Based on a one-tailed  $t$ -test, the methodology utilized by Dr. Lehn.

30. Generally, the alternative to an event study conclusion that a particular stock return was caused by company-specific information is the conclusion that the stock return was the result of random volatility. For a date on which a large stock price decline occurred, such a conclusion could potentially be justified if the date in question were selected arbitrarily. However, if the date was not selected arbitrarily, but was examined because it followed a major news announcement, attributing a large stock decline solely to random volatility becomes less reasonable.
31. This fundamental principle about statistical hypothesis testing is discussed in Shanken [1987].

“These examples demonstrate that the interpretation of a given p-value can vary substantially from one context to another. Although sample size is an important consideration, the mapping into a ‘reasonable degree of belief’ also depends on one’s prior belief about the relevant alternative(s). Given this assessment, the evidence favors the hypothesis under which it is more ‘likely’ to have been observed.”

“A Bayesian Approach to Testing Portfolio Efficiency,” by Jay Shanken, *Journal of Financial Economics*, 1987, pp. 201-202.

32. The 7 February 2001 date was not selected arbitrarily, but was a date on which the market processed corrective information about the CLASS data. The large residual stock price decline that even Dr. Lehn’s flawed test detected therefore cannot reasonably be attributed to coincidental random volatility. Rather, the proper conclusion based on the scientific evidence is that the disseminated information concerning CLASS caused the residual stock price decline observed that day.

### **DR. LEHN’S TOO NARROW WINDOW LENGTH**

33. Dr. Lehn posits incorrectly that the effect on the Pharmacia stock price of the 6 February 2001 data posting was limited to the stock price decline that occurred that day. He wrongly assumes that the disclosure had no effect on the stock price on February 7<sup>th</sup> and 8<sup>th</sup>.<sup>3</sup> While the stock price declines on February 7<sup>th</sup> and 8<sup>th</sup> were statistically significant, and the cumulative return from February 6<sup>th</sup> through the 8<sup>th</sup> was also statistically

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<sup>3</sup> Lehn Report, paragraphs 70-87.

significant, Dr. Lehn erroneously fails to associate these declines with the corrective disclosures because they did not occur on February 6<sup>th</sup>.

34. Apparently, Dr. Lehn's failure to properly attribute the 6-8 February stock price decline to the corrective disclosure that began on 6 February and continued on 7 February 2001 stems in part from his misreading of the academic literature on proper window length, in particular, the Patell and Wolfson [1984] study. In his report, Dr. Lehn provides an incomplete (and therefore misconstrued) portion of a comment Brealey and Myers made about the Patell and Wolfson study:

“As discussed in Brealey and Myers, ‘prices will adjust immediately to public information’ in an efficient market. Brealey and Myers cite a study by Patell and Wolfson (1984), which examined how companies’ stock prices reacted to public announcements of earnings and dividends and found that the major part of the adjustment in price occurs within 5 to 10 minutes of the announcement.”

**Lehn Report, paragraph 41 (internal citations omitted).**

35. The complete quote from Brealey and Myers, including the portion Dr. Lehn omitted, states specifically that the rapid speed of stock price adjustment Patell and Wolfson observed pertains only to announcements of earnings and dividends:

“A study by Patell and Wolfson shows just how fast prices move when new information becomes available. They found that, when a firm published its latest earnings or announces a dividend change, the major part of the adjustment in price occurs within 5 to 10 minutes of the announcement.”

***Principles of Corporate Finance*, 7<sup>th</sup> edition, by Richard A. Brealey and Stewart C. Myers, McGraw-Hill Irwin, 2007, p. 353 (internal citations omitted).**

36. As I noted in my June Report, Patell and Wolfson explained that less regular information releases – like the CLASS data – could impact stock prices over a more protracted period:

“It is possible that the adjustment intervals would be significantly longer for smaller firms, or for other, less regular announcements made by our sample firms.”

**“The Intraday Speed of Adjustment of Stock Prices to Earnings and Dividend Announcements,” by James M. Patell and Mark A. Wolfson, *Journal of Financial Economics*, 1984, p. 250.**

37. Not only do Patell and Wolfson state that less regular announcements could elicit more protracted stock price adjustments, but they find that even for earnings and dividend announcements, the price reaction persists beyond the first day.

“Finally, we must consider the relation between the mean return tests where trading profits largely disappear in five to ten minutes (although we do detect significant mean returns in the overnight period and at the opening of trading on the following day), and the variance and serial correlation tests where disturbances persist for several hours after public disclosure and extend well into the following day.”

“**The Intraday Speed of Adjustment of Stock Prices to Earnings and Dividend Announcements,**” by James M. Patell and Mark A. Wolfson, *Journal of Financial Economics*, 1984, p. 250.

“We find large disturbances in the correlation pattern immediately following the release of earnings numbers and dividend changes; the major portion of the announcement effect dissipates within sixty to ninety minutes, although, as in the variance tests, *statistically significant departures continue into the following day.*”  
*Ibid.*, p. 224 (emphasis added).

38. Moreover, as noted in my original report, the use of multiday event windows, which inherently recognize that stock responses may span multiple days, is common in the academic literature. Of the 21 articles reviewed in the Bruner [2002] survey article that utilized the cumulative event study methodology, as shown in Table-1 (below) 17 were found to use event windows of three days or longer.
39. Dr. Lehn’s failure to recognize that stock price reactions persist beyond the day of the announcement is at odds with the authoritative literature that even he cites. Moreover, he fails to consider that the corrective disclosure in this case was the type of information that Patell and Wolfson noted could have a more protracted effect.



<b>Table-1</b>		
<b>Study</b>	<b>Event Window</b>	<b>Length of Window</b>
Langetieg (1978)	(-120,0)	121 Days
Bradley, Desai & Kim (1988)	(-5,5)	11 Days
Jarrell & Poulsen (1989)	(-20,10)	31 Days
Lang, Stultz & Walkling (1989)	(-5,5)	11 Days
Franks, Harris & Titman (1991)	(-5,5)	11 Days
Healy, Palepu & Ruback (1992)	(-5,5)	11 Days
Kaplan & Weisbach (1992)	(-5,5)	11 Days
Berkovitch & Narayanan	(-5,5)	11 Days
Smith & Kim (1994)	(-5,5)	11 Days
Schwert (1996)	(-42,126)	169 Days
Loughran & Vijh (1997)	(-2,1250)	1,253 Days
Maquieira, Megginson & Nail (1998)	(-60,60)	121 days
Eckbo & Thorburn (2000)	(-40,0)	41 Days
Leeth & Borg (2000)	(-40,0)	41 Days
DeLong (2001)	(-10,1)	12 Days
Houston et al. (2001)	(-4,1)	6 Days
Mulherin & Boone (2000)	(-1, +1)	3 Days

**Dr. Lehn's Window Premise is Inconsistent with His Three-Day Dummy Variables**

40. Contrary to his contention that stock price reactions occur “within 5 to 10 minutes of the announcement,”<sup>4</sup> in his event study design Dr. Lehn implicitly acknowledges that stock price reactions often extend beyond the first day of an information release. For his event study regression, Dr. Lehn explains it is necessary to use dummy variables (which he calls “indicator variables”) to “remove any influence that the Complaint Days might otherwise have had on the regression model’s results.”<sup>5</sup>
41. Dr. Lehn does not control only for each of the “Complaint Days” on which the Complaint states relevant news emerged. Rather, Dr. Lehn employs dummy variables to control for the “Complaint Day,” the trading day prior, and the trading day after – a three-day window.

“To control for the Complaint Days in the regression model used in the event study analysis, I included indicator variables for the date of each Complaint Day, as well as the day before and the day after each Complaint

<sup>4</sup> Lehn Report, paragraph 41.

<sup>5</sup> *Ibid.*, paragraph 45.

Day. The indicator variables remove any influence that the Complaint Days might otherwise have had on the regression model's results.”  
**Lehn Report, paragraph 45.**

42. Due to the timing of certain “Complaint Days,” Dr. Lehn applies dummy variables for up to six consecutive trading days. If Dr. Lehn truly believes information effects are confined to the first five or ten minutes after an announcement, he would not have found it necessary to dummy out three days for each announcement mentioned in the Complaint.

#### **Dr. Lehn Conducts a Two-Day Cumulative Test**

43. Dr. Lehn further acknowledges that information may impact a stock price beyond the first day when he runs a two-day cumulative event study test for the period 6-7 February 2001.<sup>6</sup>

“Pharmacia’s residual return on February 7, 2001 was negative 2.90% and not statistically significant. Pharmacia’s two-day residual return on February 6–7, 2001 was negative 3.10% and not statistically significant.”  
**Lehn Report, paragraph 79.**

44. That Dr. Lehn considers it important to test for a significant reaction over the two days, 6-7 February 2001, implies that he accepts that a stock price reaction may extend beyond the first few minutes on the day of the announcement. Given this fact, his failure to detect the significant stock price reaction of 7 February 2001, or to extend the cumulative event study test to include 8 February 2001 (which three-day cumulative return was statistically significant), renders his analysis incomplete and his conclusion misguided.

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<sup>6</sup> While he attempts to conduct a 2-day cumulative event study for 6-7 February 2001, Dr. Lehn computes the single-day and cumulative residual returns incorrectly. The returns in Dr. Lehn’s event study are percent price changes rather than logarithmic returns. Unlike logarithmic returns, percent price changes do not aggregate residual and explained returns additively. For percent price changes, the residual return is not simply the actual return minus the explained return. As such, Dr. Lehn’s single-day residual returns are computed incorrectly. Similarly, while two logarithmic residual returns can be summed to arrive at a cumulative 2-day residual return, the percentage price changes that Dr. Lehn uses cannot be added thusly. Consequently, his cumulative residual return is also computed incorrectly.

**Dr. Lehn Adopts Multiday Event Windows in His Published Research**

45. While in the current case Dr. Lehn confines potential stock price reactions to short intervals following the corrective disclosures, in his published work he examines very long event windows to investigate price responses to announcements.

“This paper employs event study methodology to measure the stock price effects associated with merger and acquisition announcements. ... We estimate the abnormal returns for the acquiring firms on each day during the period of 5 trading days before the merger and acquisition announcements through 20 days after the announcements (i.e. [-5, 20]). As reported below, we estimate cumulative abnormal returns for acquiring firms over several windows surrounding the announcement dates.”

**“CEO Turnover after Acquisitions: Are Bad Bidders Fired?” by Kenneth M. Lehn and Mengxin Zhao, *Journal of Finance*, August 2006, p. 1768.**

“CAR is the cumulative abnormal return to acquiring firms around the announcements of their respective mergers and acquisitions, measured over several event windows, including the abnormal return on the announcement date [0], the CAR measured one trading day before through one trading day after the announcement date [-1,1], the CAR measured one trading day before through five trading days after the announcement date [-1, 5], the CAR measured five trading days before through five trading days after the announcement date [-5, 5], and the CAR measured 5 trading days before through 20 trading days after the announcement date [-5, 20].”

***Ibid.*, p. 1769.**

46. In the article from which these quotes were taken, Dr. Lehn considered event windows extending 20 days after the announcements. This treatment is inconsistent with his premise in the current case that a stock price fully adjusts to new information within minutes of an announcement.

**THE CORRECTIVE DISCLOSURE ON 6 FEBRUARY 2001 WAS PARTIALLY  
COUNTERVAILED BY COMPANY STATEMENTS**

47. One reason why the corrective disclosure that began on 6 February 2001 took multiple days to be processed by the market and incorporated into the Pharmacia stock price is that the Company’s briefing document, which was posted with the three FDA reports, partially confounded the disclosure, slowing the processing of the new information.

48. While investors would have ultimately arrived at the conclusion that the full CLASS data did not support the requested label modification, the subsequent FDA analysis and discussion facilitated that process.
49. These facts support the three-day window as the most appropriate event study timeframe.

**Defendants Briefing Document Presented and Advocated the Six-Month Data**

50. The Company's briefing document, which was posted on the FDA website concurrently with three FDA reviewer reports, contained the 6-month results as well as a justification for analyzing the six-month CLASS results. The Company's briefing document stated that due to the number of patients that withdrew from the study, the standard analysis may be "misleading" and the six-month CLASS results are more reliable to determine the safety profile of Celebrex.

"Confounding due to this differential loss of high-risk patients from the study is minimized in the six-month analysis."

**CLASS Advisory Committee Briefing Document, dated 7 February 2001, p. 40.**

"Withdrawals due to moderate-to-severe GI symptoms were also significantly higher in the diclofenac group versus the other treatment arms (9.5% for diclofenac vs. 7.5% for celecoxib and ibuprofen,  $p < 0.05$  for diclofenac vs. celecoxib). This significantly higher withdrawal rate due to moderate-to-severe GI symptoms for the diclofenac group thus led to the early withdrawal of patients at risk of an endpoint event within this treatment arm, biasing the observed event rates associated with diclofenac (i.e., informative censoring). Therefore, standard analysis and interpretation of the event rates associated in this study with diclofenac may be misleading."

***Ibid.*, pp. 42-43.**

51. Rather than correcting their alleged misrepresentations, by advocating for the conclusions based on the six-month data, the Company's briefing document perpetuated the alleged misinformation, which impeded or slowed the market's complete and correct evaluation of the CLASS results contained in the three FDA reviewer reports, which had been simultaneously posted on the FDA website on or about 6 February 2001.<sup>7</sup>

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<sup>7</sup> Affidavit of Howard R. Philips, 18 October 2010, Attachments A – C.

52. The market was further slowed or impeded in its evaluation of the entire CLASS data on 6 February 2001, because at that time it appeared to investors that the editors at *JAMA* endorsed defendants' six month analysis, having published that analysis five months earlier. It was not until August of 2001 that investors learned Defendants had deceived *JAMA* into publishing the six month analysis.

**Pharmacia's Presentation at the Merrill Lynch Conference**

53. Also on 6 February 2001, during the Merrill Lynch Global Pharmaceutical, Medical Device & Biotechnology Conference, Pharmacia CEO Fred Hassan ("Hassan") appears to have made a presentation about Pharmacia. As part of the presentation, Mr. Hassan appears to have highlighted the six-month CLASS results, citing the *JAMA* article touting Celebrex's 48%-66% reduction in ulcer complications.<sup>8</sup> Those results, based only on the six-month CLASS data, suggested a Celebrex safety advantage, while the full data set did not.
54. Consequently, the analysts and investors received a mixed message on February 6<sup>th</sup>. The corrective disclosure in the FDA reports, explaining that it was unjustified and inappropriate to conclude from the six month data that Celebrex had a safety advantage, was confounded by the Company's briefing document and possibly the Merrill Lynch presentation.

**Dr. Lehn Ignores the Defendants' Countervailing Briefing Document Posted on February 6<sup>th</sup>**

55. In his discussion of Pharmacia's stock price reaction to the release of the FDA briefing documents, Dr. Lehn asserts that "all of the allegedly material false and misleading information that the plaintiffs contend should have been revealed on April 17, 2000 was known by the market no later than February 6, 2001."<sup>9</sup> Dr. Lehn stated that he "found no other information released about Pharmacia on February 6, 2001 that conceivably could have affected Pharmacia's stock price."<sup>10</sup>

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<sup>8</sup> Exhibit 391 at DEFS 04133626.

<sup>9</sup> Lehn Report, paragraph 73.

<sup>10</sup> *Ibid.*, paragraph 74.

56. Dr. Lehn is wrong. He disregarded the Company's countervailing representations that day, including those in the Company's briefing document, which reasonably would have confused the market.
57. Considering the confounding representations made on February 6<sup>th</sup>, the complexity of the data in the posted documents, and Defendants' prior misrepresentations and omissions about the CLASS results, it is reasonable to conclude that the market required multiple days to analyze the information and fully and correctly incorporate it into the Pharmacia stock price, particularly given the complex and scientific nature of the CLASS data.

**DR. LEHN'S CONTENTION THAT THE ADVISORY COMMITTEE'S DECISION  
WAS AN UNFORESEEN DEVELOPMENT IS INCORRECT AND CONTRARY TO  
THE FACTS**

58. In his discussion of 7 February 2001, Dr. Lehn contends that the Advisory Committee's decision not to recommend a label change for Celebrex was an unforeseen intervening event, and still would have been so even if the full CLASS results had been disclosed at the beginning of the Class Period.

"It is inappropriate to use the entirety of the residual decline in Pharmacia's stock price on February 7, 2001 as a measure of alleged damages for several reasons. ... Second, any use of the February 7, 2001 residual stock price decline to measure alleged stock price inflation due to the alleged misstatements during the class period rests on a false assumption that the news on February 7, 2001 could have been disclosed earlier (e.g., at the start of the class period). Even if during the class period Pharmacia had described the CLASS study results as Plaintiffs alleged it should have, Pharmacia could not have predicted the specific reaction by the Committee in the February 7, 2001 hearing. Nor could the market have predicted the specific reaction under those circumstances."  
**Lehn Report, paragraph 80.**

59. The Advisory Committee's recommendation was not an event that was completely unforeseen and unrelated to the alleged fraud, as Dr. Lehn asserts. Rather, the recommendation was the natural consequence of the disclosure of the previously omitted facts. As such, the deliberations and recommendation served to clarify the disclosure.

60. Plaintiffs allege that Defendants concealed the full CLASS study data in order to falsely claim a GI safety advantage for Celebrex over other NSAIDs. The alleged fraud concealed the truth, *i.e.*, the full CLASS study data, in order to publish the favorable truncated data to lead investors to believe Pharmacia was likely to obtain a favorable label change from the FDA. But as Defendants knew by the beginning of the Class Period, since they had the full CLASS data at that time, and as was finally revealed to investors in February 2001, the full CLASS data showed no safety advantage to Celebrex which would merit the requested label change. Thus, the Advisory Committee's recommendation was an event that the market could have predicted before 7 February 2001 if the market had been in possession of the full CLASS data.
61. If the market had access to the full CLASS data, free of Defendants' attempts to conceal it and/or obfuscate it before 7 February 2001, the Advisory Committee's actions would have been anticipated. The Advisory Committee's recommendation on 7 February 2001 was based upon consideration of the entire study period results (including comparisons with diclofenac) which were publicly disclosed for the first time on 6 February 2001 in the form of the three FDA reports posted on the FDA's website (although this information was obfuscated by the Company's briefing document posted the same day). The full data showed no Celebrex safety advantage, and therefore indicated that the requested label modification was not warranted.
62. Indeed, after evaluating results from the entire study period including comparisons with diclofenac, the members of the Advisory Committee reached the same conclusions that the market would have reached at the beginning of the Class Period had the full CLASS data been disclosed then. The full CLASS study data did not prove Celebrex to be safer than traditional NSAIDs.

“After looking at the data presented,<sup>[11]</sup> I can come to the conclusion that I can't conclude that at the present time, so I would have to say at the present time, from what I have seen, the upper GI toxicity we are talking about—and that is a question to ask—upper GI safety appears to be similar to those, to at least again to the different presentations, I cannot say that it is different from the standard NSAIDs.

...

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<sup>11</sup> Data from the entire study period including comparisons with diclofenac were presented at the advisory committee hearing on 7 February 2001. See Affidavit of Howard R. Philips, 18 October 2010, Attachments A – C.

Again, the sponsors have said this is one study with two comparator NSAIDs. Therefore, putting the data together, I can't come up with a difference."

**Dr. Michael Wolfe, Transcript of the FDA Arthritis Advisory Committee, 7 February 2001, pp. 169-170.**

"I agree if you are going to combine both NSAID comparators together, you didn't see a difference..."

**Dr. James Williams, Transcript of the FDA Arthritis Advisory Committee, 7 February 2001, p. 170.**

"It is certainly clear that no difference has been shown for the complicated ulcer. ... So, I think that if one is talking about an advantage, it ought to show up clear through all adverse events, and not just when we look at some specific category of adverse event."

**Dr. Janet Elashoff, Transcript of the FDA Arthritis Advisory Committee, 7 February 2001, pp. 171-172.**

63. The Advisory Committee (because of the timing of the meeting shortly after the posting of the reports) announced its recommendation before analysts were able to fully understand the reports. Unlike the analysts who saw the entire study period results for the first time on 6 February 2001, the FDA had access to the full data set for months prior to the meeting. An unhurried, thorough consideration of the full data set revealed that Pharmacia would not get a removal of the NSAID GI warning as the full data set revealed that Celebrex had not proven a GI safety advantage. Thus the Advisory Committee recommendation was based upon the same information that was publicly disclosed for the first time on 6 February 2001, and was the natural and logical consequence of that disclosure.
64. Had the market had all the CLASS data at the beginning of the Class Period, it would have known then that Celebrex had not proven a GI safety advantage over the comparator NSAIDs. The market would therefore have understood that the Advisory Committee would have no basis for recommending the desired label change.
65. Dr. Lehn's depiction of the Advisory Committee's actions as being a closely contested decision, or an adjudication of a query about which reasonable people might disagree, is not supported by the evidence. Given the full CLASS data, the event was more a foregone conclusion than an unforeseen development.



**Defendants Knew At the Beginning of the Class Period That the Complete CLASS Data Did Not Support Deletion of the NSAID GI Warning**

66. Further supporting my conclusion that the market would have known the Advisory Committee would have recommended against a label change at the beginning of the Class Period if it had the full CLASS data, are internal communications by the Defendants. Internal communications reveal that Defendants knew from the start of the Class Period that the full CLASS study results did not support the desired label change.

“[Lori Shafner] *If we know that we will not achieve the original intent to modify the NSAID GI Warning* should we communicate to Pfizer Sr. Mgmt?

...

[Mona Wahba] The *data won’t support the original intent of modify the GI warning*, agree with you need to be communicated.”  
Internal Email, dated 16-17 April 2000, Exhibit 414 at DEFS 00122679 (emphasis added).

“As you review this label, we would like you to consider the following:

- Previous discussions with management regarding potential labeling scenarios once the CLASS data was available included an option to remove the GI warning.
- *Based on the results of the trial, this approach no longer seems appropriate.*”

Internal Memorandum, “Label Review Meeting,” dated 27 April 2000, Exhibit 130 at DEFS 01433613 (emphasis added).

67. Defendants knew from the start of the Class Period that the entire CLASS study results did not support deletion of the NSAID GI warning on the Celebrex product label.

**DR. LEHN’S CONTENTION ABOUT STOCK PRICE ADJUSTMENT SPEED IS INCONSISTENT WITH HIS DESCRIPTION OF THE ROLE OF ANALYST REPORTS**

68. Dr. Lehn acknowledges that the market for Pharmacia stock was efficient. As noted in my June Report, the academic literature and courts have observed that analyst coverage promotes market efficiency.
69. Dr. Lehn concurs that analysts play an important role in processing information and disseminating it to the marketplace.

“In order to provide additional context and insight regarding how the market perceived certain announcements, I examine commentary by securities analysts who followed Pharmacia. Securities analysts are investment professionals who follow a specific company (or set of companies) closely. Their ‘primary responsibility’ is:

‘...the publication of regular written reports covering the investment attributes of specific companies. These research reports have several functions. First, they review new corporate information such as earnings announcements and management changes. Second, they suggest investment ideas for stocks in the analyst’s industry, based, in part, on the new information. Third, they provide written earnings projections to the reader and present formal buy/sell recommendations to the firm’s clients.’

Hence, the views of securities analysts provide additional context that can inform an opinion as to whether information is material.”

**Lehn Report, paragraphs 36-37 (internal citation omitted).**

70. It follows that if analysts required multiple days to process the corrective disclosures about the CLASS data, the complete market price reaction would take at least that same amount of time.
71. While Dr. Lehn accepts the principles that analyst coverage facilitates the processing and dissemination of information, and that analyst reports indicate the market’s understanding of information, he fails to consider that some analysts published their analysis of the CLASS data disclosures on 7 February and 8 February 2001.

“The FDA’s written review of the Celebrex sNDA seeking modification or elimination of the NSAID class label was issued yesterday (in advance of today’s FDA Advisory Panel Meeting). These reports are more negative than anticipated, raising the possibility of a contentious Advisory Panel review today.

The FDA raised four key issues: (1) Pharmacia’s choice to analyze the 26 week data exclusively (vs. 52 week data) is incorrect; (2) Celebrex failed to show any statistically significant benefit over one of the comparator NSAIDs (diclofenac); (3) Pharmacia failed to adjust for multiple subgroup analyses, rendering even those P values less than 0.05 in doubt; and (4) ibuprofen plus aspirin was statistically superior to either Celebrex or diclofenac plus aspirin (and better than ibuprofen alone).

...

Both the Gastrointestinal Reviewer and the Statistical Reviewer so strongly disagreed with Pharmacia’s analysis of the data at the 26 week time

point that both specifically did not discuss or treat those results, focusing instead their entire discussion on the end-of-study data.

Because the event rates for diclofenac and ibuprofen plateaued after 26 weeks but continued to rise for Celebrex, the differences between Celebrex and the comparators was less robust at the end-of-study time point. In particular, the statistically significant reduction in the primary endpoint (serious upper GI events) seen in the non-aspirin subgroup at 26 weeks is not statistically significant at 52 weeks (Table I)."

**"FDA Review Of Celebrex More Negative Than Expected Panel Could Be Controversial,"** by Carl Seiden, *et al.*, J.P. Morgan Securities, analyst report, 7 February 2001, at JPMC 001610-12.

"In reviewing Celebrex, consensus among the Advisory Panel members was that PHA/PFE's Celebrex did not establish a 'meaningful safety advantage' in comparison to NSAIDs (ibuprofen and diclofenac). With the data available, the committee could not justify a change in Celebrex's label."

**"FDA Unlikely to Improve Celebrex Label,"** by Joseph P. Riccardo, *et al.*, Bear Stearns, analyst report, 7 February 2001, at DEFEX 008229.

"Celebrex shows a benefit in reducing 'symptomatic ulcers' vs other NSAIDs. Overall, Celebrex may be safer than the 'old NSAIDs', but the CLASS trial (at a dose 2-4x normal) did not convince the FDA committee."

**"PHA: FDA Reviews Celebrex & Vioxx Safety Data,"** by Mark Striker and George Grofik, Salomon Smith Barney, analyst report, 7 February 2001 (effective date is 2/8), p. 1.

"FDA Panel Rejects Label Change. An FDA Advisory Committee rejected the notion that Celebrex, a COX-2 inhibitor, has a better safety profile NSAIDs. PHA shares sold off (3+%) based on concerns that Celebrex's growth will stagnate without a label change."

**"CLASS Flunks Out,"** by Mara Goldstein, *et al.*, CIBC, analyst report, 8 February 2001, p. 1.

"Yesterday, Pharmacia presented data on Celebrex from the CLASS (Celecoxib Long-term Arthritis Safety Study) to the FDA advisory committee. The panel rejected the drug's claim that it is gentler on the stomach than the older nonsteroidal medications (NSAIDs) and recommended that the FDA deny Pharmacia's request for an improved label that would differentiate it from the older NSAIDs, which contain a warning for gastrointestinal toxicity."

**"Pharmaceuticals: Disappointing FDA Review of GI Safety Data for Celebrex,"** by Jeffrey Chaffkin and C.J. Sylvester, UBS Warburg, analyst report, 8 February 2001, at DEFEX 009148.

“The FDA Arthritis Advisory Committee recommended no change in Celebrex’s label during discussions Wednesday. This labeling posture resulted from statistical complications within the CLASS clinical trial, including Celebrex’s failure to achieve a statistically significant improvement in its complicated ulcer primary endpoint and FDA requests for further study on the effects of COX-2 in combination with aspirin.”  
**“No Change Recommended for Celebrex Labeling: ‘Status Quo’ Mildly Disappointing, but Manageable,”** by Kenneth Kulju, *et al.*, Credit Suisse First Boston, analyst report, 8 February 2001, p. 1.

72. While Dr. Lehn was aware of these analyst reports,<sup>12</sup> he fails to appreciate that they indicate that the CLASS data disclosure was voluminous and complex to an extent that the market required the time through 8 February 2001 to digest it and incorporate it into the Pharmacia stock price.
73. Dr. Lehn contends the price movements on February 7<sup>th</sup> and 8<sup>th</sup> were unrelated to the disclosure that began on February 6<sup>th</sup> and continued on February 7<sup>th</sup>. His contention is inconsistent with the facts of this case, with financial principles, with the literature Dr. Lehn cites, with his own methodology in this case, and with his prior published work. The price reaction to the CLASS disclosure extended to February 7<sup>th</sup> and 8<sup>th</sup>. The fact that the Pharmacia Pharmaceuticals Stock Price movements on those days and cumulatively over 6-8 February 2001 were statistically significant proves that the misrepresentations and omissions about the CLASS data inflated the Pharmacia stock price and caused investor losses.

**ANALYZING THE EFFECT OF VIOXX-RELATED INFORMATION THAT  
EMERGED ON 8 FEBRUARY 2001**

74. Dr. Lehn contends that Pharmacia’s statistically significant stock price decline on 8 February 2001 was caused by the news that Merck’s competing product, Vioxx, received approval from the FDA for a favorable label change. Dr. Lehn reasons that significant good news for Merck and Vioxx would be significant bad news for Pharmacia and Celebrex.

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<sup>12</sup> See for example: Lehn Report, paragraph 78.

“Good news about Cox-2 Inhibitors would move Pharmacia and Merck’s prices in the same direction; good news for Vioxx relative to Celebrex would be expected to move Pharmacia and Merck’s prices in the opposite direction.”

**Lehn Report, paragraph 45, footnote 15.**

75. To assess whether the Pharmacia stock price decline on 8 February 2001 was caused by the positive development pertaining to Vioxx, I conducted an event study on Merck stock to determine if the new Vioxx information was significant. Dr. Lehn stated that this is the correct approach to determine whether the information is both new and important to investors.

“If the information released on a particular day is both new and material to investors, then the residual return on the event date should be significantly different from zero.”

**Lehn Report, paragraph 46.**

76. In particular, one would reasonably expect that material news about Vioxx would have a significant impact on the price of Merck stock because Vioxx was extremely important to Merck. Merck was bracing for impending patent expirations and was counting on Vioxx to maintain company revenues and profit.

“Merck is counting on Vioxx to help the company weather upcoming patent expirations on three of its best-selling drugs.”

**“FOCUS-FDA Panel Backs Merck’s Vioxx Painkiller,” by Lisa Richwine, *Reuters News*, 21 April 1999.**

“Merck needs Vioxx to be a winner. After years of rapid sales and profit growth, patents on some of its biggest sellers will soon expire, opening the door to less-expensive generic versions. The company is also grappling with a slowdown in sales growth of its big cholesterol-drug franchise and was recently hit with a delay in developing a new antidepressant.”

**“Merck’s Financial Health Hinges on Sales of Its New Arthritis Pill,” by Robert Langreth, *Dow Jones Business News*, 14 April 1999.**

“But Dr. Scolnick [the president of Merck Research Labs] gives plenty of credit to the way things broke Merck’s way during Vioxx’s development. ‘If those first two compounds had failed in human trials and we had had

by chance to rely on the fifth or sixth one' years later, he says, 'we would be a very different company.'"

**"The Cure: With Big Drugs Dying, Merck Didn't Merge – It Found New Ones – Some Inspired Research, Aided By a Bit of Luck, Saves Company's Independence – The Path to a Novel Painkiller," by Gardiner Harris, *Wall Street Journal*, 10 January 2001.**

77. In 2001, Vioxx accounted for 13% of Merck's sales.<sup>13</sup> Analysts estimated the gross profit margin on Vioxx to be in excess of 90%.<sup>14</sup> With that profit margin, Vioxx accounted for approximately 13.1% of Merck's gross profit in 2001.<sup>15</sup> Bear Stearns analysts anticipated that Vioxx would account for 17.1% of Merck's revenue in 2002.<sup>16</sup> Consequently, Merck relied on Vioxx for a substantial portion of its current and forecasted sales.
78. Nonetheless, as explained next, the news about Vioxx that emerged on 8 February 2001 had no statistically significant impact on the price of Merck stock.
79. I constructed the Merck event study in the same fashion as I conducted the Pharmacia Pharmaceuticals Stock Price event study in my June Report. I used the same Market Index for the market factor, and I used the Pharmaceutical Index (which had Pharmacia, Pfizer, and Merck removed) for the sector index.<sup>17</sup> I ran the regression over the same control period, 19 October 2000 through 18 October 2001.
80. I utilized dummy variables for each day from 6 February through 12 February 2001 to control for the potential effects of both Vioxx- and Celebrex-related news that was released during this period.
81. On 7 February 2001, in addition to the Advisory Committee's decision on Celebrex, the FDA posted reviewer reports on its website that contained and analyzed the VIGOR study data. Similar to the CLASS briefing documents, these reviewer reports were posted prior to the Advisory Committee's review of the VIGOR study that would occur the following day.
82. Merck stock prices, dividends, and returns are presented in Exhibit-5. The regression results are presented in Exhibit-6. The event study results are shown in Exhibit-7.

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<sup>13</sup> Deutsche Banc Alex. Brown, Merck analyst report, 29 January 2001, p. 5.

<sup>14</sup> Natexis Bleichroeder Inc., Merck analyst report, 1 October 2004, p. 13.

<sup>15</sup> Merck & Co., Inc. Form 10-K for the Fiscal Year Ended 31 December 2003, filed 10 March 2004, p. 21.

<sup>16</sup> "FDA Unlikely to Improve Celebrex Label," by Joseph P. Riccardo, *et al.*, Bear Stearns, Pharmacia analyst report, 7 February 2001, at DEFEX 008231.

<sup>17</sup> In its Proxy statement Merck compared its performance to the Dow Jones Pharmaceutical Index. See: Merck & Co., Inc. Form DEF 14A, filed 22 March 2001, p. 22.

83. As described next, the news about Vioxx, which Dr. Lehn considers positive enough to cause the price of Pharmacia stock to decline significantly, had no significant impact on the price of Merck stock. Merck's stock price did not rise significantly on 8 February 2001, over the three-day period beginning on 7 February 2001, or over the three-day period beginning 8 February 2001. By Dr. Lehn's reasoning, the Vioxx news was not new material good news for Vioxx, therefore this news could not have been responsible for Pharmacia's decline.
84. Thus, as I concluded in my June Report, the cause of the statistically significant decline in Pharmacia's stock price on 8 February 2001 was news specific to Pharmacia and the disclosures about CLASS.

### **Merck Event Study Results**

85. On 8 February 2001, Merck's stock price increased 1.36%. The Market Index declined 0.65%, and the Pharmaceutical Index rose 0.43%. According to the regression model, the Merck stock residual return that day was 0.95%. This is not an unusually large one-day residual increase. With a *t*-statistic of 0.65, this residual return is not statistically significant at the standard 5.0% significance level, or any other acceptable level (p-value equals 0.517).
86. The following day, 9 February 2001, Merck's residual return was -0.46%. This too is not an unusually large one-day residual return. With a *t*-statistic of -0.32, this residual return is not statistically significant at the standard 5.0% significance level, or any other reasonable significance level (p-value equals 0.752).
87. The following trading day, 12 February 2001, Merck's residual return was -0.48%, again, not an unusually large one-day residual return. With a *t*-statistic of -0.33, this residual return is not statistically significant at the standard 5.0% significance level, or any other reasonable significance level (p-value equals 0.743).
88. Over the three-trading-day period, 8-12 February 2001, Merck's stock price increased 1.37%. Over the same period, the Market Index return was -1.06%, and the Pharmaceutical Index return was 1.54%. The three-day explained return for Merck's stock according to the regression model is positive 1.37%, which is the change one would



expect in the price of Merck stock on account of market and sector effects absent any Merck-specific information.

89. The residual three-day return for Merck stock was 0.01%. On a residual return basis, Merck stock barely budged over the three day period. This three-day residual return is associated with a *t*-statistic value of virtually zero. The residual return is not statistically significant at the standard 5.0% significance level, or any other reasonable level (p-value equals 0.998).
90. As shown in Exhibit-7, Merck's residual return over the three days beginning on February 7<sup>th</sup> was similarly not significant.
91. Nonetheless, Dr. Lehn attributes 94% of Pharmacia's gross stock price decline on 8 February 2001 to the Vioxx news.<sup>18</sup> However, if the Vioxx news was not measurably beneficial for Merck, following Dr. Lehn's logic it could not have been so material as to be responsible for the large and highly statistically significant decline in the price of Pharmacia stock that occurred on 8 February 2001.

#### **INTRADAY PRICE MOVEMENTS ON 8 FEBRUARY 2001**

92. Dr. Lehn relies on intraday stock price data to support his argument that the significant decline in the Pharmacia stock price on 8 February 2001 was due to that day's news about Vioxx labeling rather than the corrective disclosures about CLASS.
93. According to Dr. Lehn, the Advisory Committee released its decision to recommend that Merck be allowed to amend the Vioxx label at 3:06 p.m. on 8 February 2001. He also contends that a major portion of the full day's decline in the price of Pharmacia stock occurred after 3:00 p.m., and therefore must have been the result of the FDA Advisory Committee's decision pertaining to the Vioxx label.

“Pharmacia's residual return on February 8, 2001 was negative 5.59%, which is statistically significant. The major news about the February 8, 2001 Vioxx hearing was that the FDA Advisory Panel was going to allow Merck to add safety data from its study to the Vioxx label. When this information was released at approximately 3:00 p.m., Pharmacia's stock price declined by approximately \$2.50, or 4.45%.”  
**Lehn Report, paragraph 84.**

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<sup>18</sup> Lehn Report, paragraph 84.



94. There are numerous flaws in Dr. Lehn's argument that Pharmacia's intraday price changes indicate the Vioxx news was responsible for the large decline that day. In addition to the fact that the Vioxx news did not cause a statistically significant change in the Merck stock price, and that Dr. Lehn did no comparable analysis on Merck's intraday stock prices, Dr. Lehn's analysis of Pharmacia's intraday prices is rife with factual and methodological errors.

### **Factual Errors in Dr. Lehn's Intraday Analysis**

#### **Dr. Lehn Measures the Price Changes Incorrectly**

95. According to Dr. Lehn, the price decline between 3:06 p.m. and the close of trading on February 8<sup>th</sup> was \$2.50. I attempted to confirm Dr. Lehn's quantitative conclusion by examining the intraday stock price data obtained from the Trade and Quote ("TAQ") database. According to the TAQ data, the highest price for Pharmacia stock after 3:06 p.m. was \$55.40 per share. Pharmacia's closing stock price was \$53.00 per share, or \$2.40 per share lower than the highest price after 3:00 p.m. (which occurred at 3:10 p.m.).<sup>19</sup> Consequently, Pharmacia's stock price fell at most \$2.40 per share after the time Dr. Lehn contends the Vioxx announcement was made, not the \$2.50 per share he reports.
96. The price decline from the precise time when Dr. Lehn contends the announcement was made was even less than \$2.40 per share. The last trade prior to 3:06 p.m. occurred at a price of \$55.02 per share. From this price to the closing price, the decline was \$2.02 per share – again, not the \$2.50 per share Dr. Lehn claims. This decline is \$0.48 per share, or 19%, less than the drop that Dr. Lehn attributes to the Vioxx news.

#### **Dr. Lehn Sets the Time of the Vioxx News Incorrectly**

97. It appears that Dr. Lehn is mistaken about when the market learned that the Advisory Committee would recommend a Vioxx label change. On page 27 of his report, Dr. Lehn states the information was released at approximately 3:00 p.m. on 8 February 2001. In his Exhibit 11, he times it more precisely at 3:06 p.m.

“The major news about the February 8, 2001 Vioxx hearing was that the  
FDA Advisory Panel was going to allow Merck to add safety data from its

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<sup>19</sup> Closing and opening stock price data obtained from CRSP.

study to the Vioxx label. When this information was released at approximately 3:00 p.m., Pharmacia's stock price declined by approximately \$2.50, or 4.45%."

**Lehn Report, paragraph 27.**

"3:06 PM - A federal panel recommended that Merck & Co.'s (MRK) Vioxx add information to its label saying the drug causes fewer ulcers than naproxen."

**Lehn Report, Exhibit 11, citing *Dow Jones Newswires*.**

98. While a show of hands recapping the morning's deliberations was taken at approximately 3:00 p.m., the transcript of the Committee's deliberations shows that the meeting's participants had expressed their views about Vioxx labeling earlier in the day.

"[Dr. Lawrence Goldkind, Gastrointestinal Review]: To briefly review the results, these have been shown previously, just formatted differently. Vioxx compared to naproxen, the rate, either per 100 patient years or cumulative rate, did show a risk reduction, 0.46, with a highly statistical significant p value."

**"FDA Arthritis Advisory Committee Hearing Transcript; re: NDA 21-042/S007, Vioxx (Rofecoxib, Merck)," dated 8 February 2001, p. 103, prior to the 12:20 p m. lunch break at p. 146.**

"[Dr. Goldkind]: In terms of the generalizability of GI safety, as the sponsor has noted, Vioxx did have a substantial decrease in risk for the PUBs and complicated PUBs, as noted here."

***Ibid.*, p. 106, prior to the 12:20 p m. lunch break at p. 146.**

"[Dr. Maria Lourdes Villalba, Medical Officer]: My answer would be that we have a label that has a GI warning for non-steroidals and, based on this study, the sponsor is proposing to downgrade that label and move it to the precautions section, and be different from the other NSAIDs, and I think that the fact that we still have reports in postmarketing of these kinds of events supports the fact that we shouldn't be changing well, ***I mean modifying the label, yes***, but a dramatic change in the label, I think that is not warranted."

***Ibid.*, p. 129, prior to the 12:20 p m. lunch break at p. 146 (emphasis added).**

"[Dr. Steven Nissen, Cardiovascular And Renal Drugs Advisory Committee Member]: If I could just amplify on that for a moment, we saw a very strong message about some reduced incidence of GI effects and I happen to share Dr. Wolfe's perspective that these are not trivial events."

***Ibid.*, p. 168.**

“[Dr. M. Michael Wolfe, Gastrointestinal Drugs Advisory Committee Member]: I am comment only on the GI because that is what I am here for. I am a firm believer in setting forth the hypothesis, designing a study appropriately, checking the results, and if the results match your hypothesis your primary goal has been achieved. I think the data both presented by Merck and by the FDA show that there is, indeed, a decreased risk of GI toxicity associated with the use of this drug. No matter what arguments can be made about, well, was it because of naproxen being the comparator I don’t know. The study was designed. It was approved by the FDA. I think we have to go with what the results showed. I think in that regard I have to say that there is decreased risk of GI events. Endoscopically as well as outcomes show a parallel decrease in the rate of GI complications.”

*Ibid.*, pp. 185-186.

“[Dr. James H. Williams, Jr., Advisory Committee Member]: I agree with Dr. Wolfe that I think they have met the burden of proof. Now, I don’t think a single comparison is generalizable to all NSAIDs but I think they do have to change the label to say that in the one study that was done it was shown to make a difference.

*Ibid.*, p. 186.

“[Dr. Steven Nissen:] Well, I am just a poor cardiologist so I don’t have a lot of sophistication about the GI tract, but it seems to me that we can’t make this like it is in the Olympics. When you pole vault, you know, you go over a height and then somebody comes around and says, ‘well, okay, you made that height; we’re going to put another bar up for you to go over.’ I mean, it seems to me the sponsor here did a very large, probably pretty expensive study, with the advice and consent of the FDA. They created this template. They made those goals very clear from the very beginning. They achieved not a marginal amount of statistical significance on the GI side but an unequivocal statistical significance. ***So, the statement that rofecoxib is safer, from the gastrointestinal point of view, with respect to the endpoints that were used over naproxen is a fact, in my view, and not a marginal one, and I think that should be reflected in the product literature.***”

*Ibid.*, p. 188 (emphasis added).

“[Dr. David Wofsy, Consultant and Expert Arthritis Advisory Committee Consultant]: I have been convinced by this morning’s data that, at least with respect to some of the other non-steroidals on that continuum, they have less GI toxicity.”

*Ibid.*, p. 190.

“[Dr. Ileana Pina, Cardiovascular And Renal Drugs Advisory Committee Member]: I agree that the sponsor has proven what they meant to prove in a restricted population of rheumatoid arthritis patients who had no aspirin.”  
*Ibid.*, p. 192.

“[Dr. Byron Cryer, Guest Expert]: But I actually also fall in agreement with my colleague here, Dr. Wolfe, and that is that with respect to these labeling considerations what drives the label is a process, a process that you define ahead of time, and there are rules that are inherent in that process that drives the label.”  
*Ibid.*, pp. 197-198.

“[Dr. Steven Nissen:] I would change the label.”  
*Ibid.*, p. 199.

“[Wendy McBair, Consumer Representative]: I think the label should reflect exactly what we know and what we learned from the study that was done.”  
*Ibid.*

“[Dr. James H. Williams]: I will give Dr. Wofsy’s yes.”  
*Ibid.*, p. 202.

99. At approximately 3 o’clock there was a show of hands recapping the morning’s deliberations, but the meeting participants had already expressed their opinions earlier.

“[Dr. E. Nigel Harris, Acting Chairperson]: What I am going to do is just to carry that message that, in fact, one does have to weigh the benefits of one organ system compared to sort of the overall risk benefit, whatever. I will actually ask for a vote with respect to whether or not we actually should advise that there might be some way of framing that benefit in one system and the issue of overall benefit. Do I get a sense from the committee that we agree that there should be some mention made of that? Let me have a show of hands, yes or no.

[Show of hands]

Is there any disagreement?

[No show of hands]

Any abstentions?

[No show of hands]

So, that was unanimous. There are two general questions that have been posed, and I want to read the first of them yes, Dr. DeLap?”  
*Ibid.*, pp. 213-214.

100. That the Committee members had already expressed their opinions on the matter prior to the show of hands was noted explicitly by Dr. Harris.

“[Dr. Harris]: What I am going to ask now is whether or not in your opinion as I am going around the room, you believe the warning label should be changed with respect to GI toxicity. Keep your remarks brief, please, because I think *most of you have had an opportunity to make a statement.*”

“FDA Arthritis Advisory Committee Hearing Transcript; re: NDA 21-042/S007, Vioxx (Rofecoxib, Merck),” dated 8 February 2001, p. 197.

101. That the market learned of the Committee’s intentions hours prior to the time Dr. Lehn claims the Vioxx news arrived is evident in an *Associated Press* wire, made available on *Bloomberg*, which was time stamped 12:51 p.m. (eastern time).

“The arthritis drug Vioxx appears to cause fewer ulcers than the older painkiller naproxen and its label should say so, the government’s scientific advisers decided Thursday in a boon for maker Merck & Co. But the panel didn’t have all good news for Merck: Vioxx should retain its strong warning that it can cause ulcers just like some other older, cheaper painkillers – and doctors and patients should be warned that it might carry a heart risk, too.”

“Scientists Advise on New Drug Vioxx,” *Associated Press Wire*, 8 February 2001, 12:51:32 (17:51 GMT).

#### Price Response Following the *Associated Press* Wire

102. As shown in Exhibit-8, the announcement at 12:51 p.m. was followed immediately by an *increase* in the price of Pharmacia stock, not a decrease. The first trade prior to 12:51:32 p.m. was at a price of \$55.49 per share. Between that time and 1:09:18 p.m. the price of Pharmacia stock rose \$0.56 per share to \$56.05 per share. The immediate price response following the *Bloomberg* article about the Advisory Committee’s decision was therefore a rise in price of more than 1%, not a decline as Dr. Lehn contends.

103. To be consistent with his prior opinion that information is assimilated in five to ten minutes, this price movement would indicate to Dr. Lehn that the Vioxx news reported by *Bloomberg* caused the Pharmacia stock price to rise and therefore could not be responsible for the day's decline.

Pharmacia Stock Had Declined Prior to the Vioxx Announcement

104. Dr. Lehn also neglects to analyze movements that occurred in the price of Pharmacia stock prior to 3:00 p.m., and thus fails to observe that Pharmacia stock declined from the closing price of \$56.13 per share on 7 February 2001 to \$54.30 per share by 10:40 a.m. on 8 February 2001, indisputably before the Vioxx announcement on 8 February. From the prior day's close to this mid-morning point, the price declined \$1.83 per share, or 3.3%, which amounted to 58.5% of the total decline for the day.
105. If Dr. Lehn had controlled for the chemical and agricultural business by factoring out the value of New Monsanto, as I did when I derived the Pharmacia Pharmaceuticals Stock Prices, he would have observed an even steeper price decline occurring prior to the Vioxx announcement. The opening Pharmacia Pharmaceuticals Stock Price that day was \$50.48 per share. This represents a 0.6% decline from the previous day's closing price of \$50.78. Between the opening of trading and 10:40 a.m., the Pharmacia Pharmaceuticals Stock Price continued to decline, reaching a low of \$48.87, or a 3.8% decline from the previous day's close. A 3.8% decline represents approximately 60% of the total decline experienced that day.
106. Dr. Lehn fails to consider the stock price slide in morning trading on February 8<sup>th</sup>, which appears to be a continuation of the previous day's reaction to the corrective disclosure.

Methodological Errors in Dr. Lehn's Intraday Analysis

Dr. Lehn Neglects to Control for Market and Peer Effects, Or for the Value of New Monsanto

107. Dr. Lehn's purported intraday stock price analysis suffers from his lack of control for market and peer group effects. In his discussion of event study analysis in general, Dr. Lehn rightfully acknowledged that it is necessary to control for market and peer group effects.

“To perform event study analyses in this matter, I examined the relation between Pharmacia’s stock returns and the stock returns of general market indices and Pharmacia’s industry peers.”

**Lehn Report, paragraph 44.**

“In this case, I used the NYSE Index (“NYSE index”) and a Competitor Index of peer firms to control for movements in the market and peer company indexes during the control period.”

***Ibid.*, paragraph 45.**

108. While he accepts that controlling for market and peer effects is a necessary and important step, in his intraday analysis Dr. Lehn makes no effort to control for these factors. Nor does Dr. Lehn control for information affecting Pharmacia’s chemical and agricultural business, by factoring out the value of New Monsanto as I did, or in any manner whatsoever.
109. Consequently, Dr. Lehn cannot rule out that the Pharmacia stock price movements he observes after the Vioxx announcement may have been caused by price movements in the overall stock market or peer group, or information relating to New Monsanto. Similarly, Dr. Lehn did not examine Pharmacia’s residual returns prior to the Vioxx announcement. Consequently, Dr. Lehn did not do the requisite analysis to attribute the intraday price movements on 8 February 2001 to any one particular factor as opposed to another.

Dr. Lehn Ignores the Noise and Errors in Intraday Price Data

110. The academic literature addresses numerous unique problems and challenges associated with intraday data. Dr. Lehn, however, ignores these. For example, as the observational frequency of pricing data increases from daily to intraday, the ratio of noise-to-information in computed returns generally increases.

***“Raw returns measurement***

The presence of noise in the price data and the fact that stocks trade at discrete time intervals means that returns are measured with error and are frequently unobservable. This affects both how returns are calculated and how to deal with nontrading intervals. Although these issues also exist at the daily level, they are more important at the intraday level.

### **Logarithmic vs. proportional returns**

There are two standard methods for calculating returns: the proportional return  $[(P_t + D_t)/P_{t-1}] - 1$  and logarithmic return  $\ln[(P_t + D_t)/P_{t-1}]$ , where  $P$  and  $D$  are the price and dividends, respectively.

When proportional returns are calculated, any noise present in observed prices will cause the measured security returns to be biased upward. At the intraday level, two systematic sources of noise can be identified: the bid/ask spread and price discreteness (see Dravid 1988). Blume and Stambaugh (1983) find that when daily returns are calculated, the magnitude of the bias for low-priced stocks (averaging ~ \$5) is 0.051 percent, which is approximately one-third of the average daily return of 0.141 percent. The effect of the bias caused by the bid/ask spread and price discreteness on higher-priced stocks at the daily level is negligible. For shorter time periods, however, the effect of this bias will become greater, even for relatively high-priced stocks if the magnitude of the 'true' return decreases. Therefore, at the intraday level, it seems appropriate to be concerned with this issue. In this paper, log returns are used because they eliminate the bias in returns induced by the bid/ask spread and price discreteness (see Mucklow 1991)."

**"Market Microstructure: Effects on Intraday Event Studies," by Belinda Mucklow, *Contemporary Accounting Research*, Spring 1994, p. 357 (internal citations omitted, emphasis in original).**

111. The statistical problems arising from noise in intraday data are well documented and discussed widely in the literature.

"Unfortunately, unlike those low frequency time series that are homogeneously spaced, tick-by-tick transactions of different assets usually occur randomly and asynchronously; in addition, with high frequency data comes market microstructure noise."

**"High-Frequency Covariance Estimates With Noisy and Asynchronous Financial Data," by Yacine Aït-Sahalia, et al., *Journal of the American Statistical Association*, December 2010, p. 1504.**

112. Not only did Dr. Lehn ignore these problems described in the literature, but he used proportional returns rather than logarithmic returns, which as noted by Mucklow [1994], exacerbates the problem.

### Dr. Lehn Ignores the Special Statistical Testing that Intraday Price Analysis Requires

113. The statistical properties of intraday returns are known to differ from those of daily returns, in ways that require specialized statistical testing.



“Little is known about the distribution of intraday stock returns, especially the distribution of returns conditional on some event like a new equity issue announcement. Thus, it is appropriate to test the robustness of the parametric results discussed above with nonparametric tests. The bootstrap, developed by Efron (1982) and others, is one of several resampling plans that can be applied in situations where standard parametric techniques for statistical inference are inappropriate.”

“**Announcement Effects of New Equity Issues and The Use of Intraday Price Data,**” by Michael J. Barclay and Robert H. Litzenberger, *Journal of Financial Economics*, 1988, p. 79.

114. Not only did Dr. Lehn not conduct the specialized testing required when working with intraday data according to Barclay and Litzenberger [1988] (e.g. bootstrapping or non-parametric tests), he did no formal statistical testing at all. For these reasons as well, Dr. Lehn cannot conclude that the intraday price movements on 8 February 2001 were caused by any one particular factor as opposed to another.

**Dr. Lehn Fails to Consider Pharmacia Stock’s Intraday Price Movement On 7 February 2001**

115. If Dr. Lehn believes that the best way to determine a stock’s reaction to specific news is to informally analyze intraday trading data, which I disagree with, it follows logically that in order to determine what news Pharmacia’s stock price reacted to on 7 February 2001 he should have examined Pharmacia stock’s intraday price data on that day as well.
116. To test Dr. Lehn’s incorrect conclusion that Pharmacia’s large stock price decline on 7 February 2001 was caused by the FDA Advisory Committee’s announcement, which “entered the public press at 2:25 p.m.”<sup>20</sup> I examined the intraday trading data of the Pharmacia Pharmaceuticals Stock Price in the same manner Dr. Lehn attempted to analyze the February 8<sup>th</sup> intraday data. As shown in Exhibit-9, and detailed below, the majority of the Pharmacia Pharmaceuticals Stock Price decline occurred hours before the FDA Advisory Committee’s announcement.
117. On 7 February 2001, the Pharmacia Pharmaceutical Stock Price declined 3.15%, or \$1.62 per share. That day, the opening Pharmacia Pharmaceuticals Stock Price was \$51.09 per

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<sup>20</sup> Lehn Report, paragraph 76.

share, representing a decline of \$1.32 per share from the previous day's closing price of \$52.41 per share.

118. By 10:25 a.m. (four hours prior to 2:25 p.m. when according to Dr. Lehn the FDA Advisory Committee decision was released to the public) the Pharmacia Pharmaceuticals Stock Price was \$50.90 per share, or \$1.51 per share lower than the previous day's closing price. The \$1.51 decline in the Pharmacia Pharmaceuticals Stock Price represents 92.9% of the observed stock price decline on 7 February 2001.
119. While the Pharmacia Pharmaceuticals Stock Price is the more appropriate variable to analyze for assessing the impact of news related to Celebrex, for comparison purposes and because Dr. Lehn focused on the Pharmacia stock price without removing the value of New Monsanto, I also analyzed the intraday trading data for Pharmacia stock. On 7 February 2001, Pharmacia's stock price declined \$1.52 per share, or 2.7%. By 10:25 a.m. the Pharmacia stock price declined \$1.50 per share (or 2.6%) from the previous day's closing price. This early decline represents 98.7% of the total decline in the Pharmacia stock price that occurred that day. It is particularly noteworthy that from 2:30 p.m. (the first five minutes after the 2:25 p.m. announcement) to the close of trading, Pharmacia's stock price *increased* from \$55.75 per share to \$56.13 per share, a rise of \$0.38 per share.
120. The intraday data clearly show that the declines in Pharmacia Pharmaceuticals and Pharmacia occurred prior to the Advisory Committee's 2:25 p.m. decision regarding Celebrex.
121. If one were to accept Dr. Lehn's analysis of intraday data as reliable, which I do not, then it would follow that the intraday data from February 7<sup>th</sup> contradicts Dr. Lehn's conclusion about what caused the price drop that day. Dr. Lehn would have to conclude that the Advisory Committee's decision did not cause the day's price decline.
122. While Dr. Lehn embraces intraday price analysis for his purpose of arguing that the February 8<sup>th</sup> price declines were caused by Merck news, he fails to apply that same analysis to February 7<sup>th</sup>, when such analysis would contradict his conclusions.
123. Nonetheless, for the methodological reasons stated above, the manner in which Dr. Lehn analyzes intraday return data is unreliable. The flaws in Dr. Lehn's analysis as well as the facts of this case support event study analysis with a three-day window as the appropriate analytic methodology.

**THE SCIENTIFIC BASES DR. LEHN OVERLOOKED**

124. Dr. Lehn states that he observes no scientific basis indicating that the alleged misrepresentations and omissions about CLASS inflated Pharmacia's stock price. As shown in this report, numerous scientific bases are present, but overlooked or ignored by Dr. Lehn.
125. Dr. Lehn fails to observe the statistical significance of the Pharmacia stock price decline that occurred on 7 February 2001 due to numerous flaws in his analysis. His event study fails to appropriately control for the effects of Pharmacia's chemical and agricultural business on the Company's stock price. His choice of peer companies is neither comprehensive nor consistent with the peers identified by the Company. Dr. Lehn inappropriately dismisses the large residual stock price decline on 7 February 2001 that even his flawed test detects. Consequently, he overlooks the inescapable conclusion that the Pharmacia stock price decline on 7 February 2001 was caused by information concerning CLASS.
126. Dr. Lehn fails to associate the statistically significant declines on February 7<sup>th</sup>, February 8<sup>th</sup>, and cumulatively from February 6<sup>th</sup> through the 8<sup>th</sup> to the corrective disclosures due to his improperly short event window.
127. Dr. Lehn's conclusion that the statistically significant decline in Pharmacia stock on 8 February 2001 was caused by Vioxx news is at odds with his own logic and analysis. Due to the fact that the Vioxx news was not measurably beneficial for Merck, it could not have been so material as to be responsible for the large and highly statistically significant decline in the price of Pharmacia stock that occurred on 8 February 2001.
128. Not only does Dr. Lehn's analysis of intraday stock price data have numerous fatal factual and methodological errors, which render his conclusions unreliable, but Dr. Lehn's failure to examine the intraday stock price data on 7 February 2001 renders his analysis incomplete. Applying the same analysis to February 7<sup>th</sup> that he applied to February 8<sup>th</sup>, leads to findings incompatible with his loss causation conclusions.

129. Dr. Lehn fails to consider how the Company's briefing document that was posted on or about 6 February 2001 confounded the corrective disclosure, slowing the market's revaluation of Pharmacia stock.
130. Dr. Lehn's depiction of the Advisory Committee's actions on 7 February 2001 as being an unforeseen and unrelated event is not supported by the facts of the case.
131. Dr. Lehn's flawed analysis presents no basis to alter my conclusion that the alleged misrepresentations and omissions caused the price of Pharmacia stock to be artificially inflated over the course of the Class Period, and caused investor losses when ultimately corrected.

### **CRITIQUE OF THE FIORINO REPORT**

132. Dr. Fiorino contends that the allegedly undisclosed CLASS results were "not material," that Pharmacia's stock was not "falsely elevated" during the Class Period, and that the release of the entire CLASS results did not "cause a decline" in Pharmacia's stock price.<sup>21</sup>
133. However, Dr. Fiorino supports none of his conclusions with generally accepted scientific analysis. Rather, his conclusions are essentially conjecture. Moreover, his opinions are internally inconsistent and run contrary to established empirical facts.

### **Dr. Fiorino Draws Loss Causation Conclusions, But Runs No Event Study**

134. Dr. Fiorino opines that the CLASS disclosures "did not result in a meaningful change in Pharmacia's stock price."

"[T]he disclosure of the allegedly withheld results from CLASS did not cause a decline in Pharmacia's stock price."

**Fiorino Report, p. 6.**

"The disclosure and complete dissemination of the allegedly previously undisclosed results of CLASS study on February 6, 2001 in the FDA Arthritis Advisory Committee briefing documents (what should have been, in the Plaintiffs' construction, the end of the 'alleged scheme'), did not change analysts' forecasts for future Celebrex sales or Pharmacia's

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<sup>21</sup> Fiorino Report, p. 6.

future earnings, did not alter the prescription trends for Celebrex, and did not result in a meaningful change in Pharmacia's stock price."

*Ibid.*

"Moreover, the disclosure of those results was not associated with a decline in Pharmacia's stock price on February 6 and did not cause or contribute to the Pharmacia stock price decline on February 7, 2001; rather, the Advisory Committee vote was the cause of the February 7 stock price decline."

*Ibid.*, p. 32.

"Specifically, Pharmacia's stock price declined on February 7 because the FDA Arthritis Advisory Committee vote against a Celebrex label change, and Pharmacia's stock price declined on February 8 because the same Committee voted in favor of a label change for Vioxx, Celebrex's competitor."

*Ibid.*, pp. 27-28.

135. While he draws conclusions about what did and did not cause the Pharmacia stock price to decline, Dr. Fiorino ran no event study – the analysis generally accepted to be the appropriate methodological tool for determining whether or not specific information caused a stock price movement.
136. Authoritative articles in the finance literature are clear that event study analysis is the proper tool for the job. For example:

"Economists are frequently asked to measure the effects of an economic event on the value of firms. On the surface this seems like a difficult task, but a measure can be constructed easily using an event study. Using financial market data, an event study measures the impact of a specific event on the value of a firm."

"Event Studies in Economics and Finance," by A. Craig MacKinlay, *Journal of Economic Literature*, March 1997, p. 13.

137. Event studies are also generally accepted as the appropriate tool in forensic settings to answer questions of causation and materiality.

“The most important reason to consider the use of an event study is that it is likely to provide a highly objective methodology for calculating the magnitude of damages and the materiality of the event that may have caused the damages.”

“**Materiality and Magnitude: Event Studies in the Courtroom,**” by David Tabak and Frederick Dunbar, in *Litigation Services Handbook*, 3<sup>rd</sup> Edition, John Wiley & Sons, New York, 2001.

138. Dr. Fiorino acknowledges that the event study methodology is the generally accepted methodology for assessing causation and materiality, and that his approach is different.

“I understand that the typical method used for assessing materiality in securities litigation is the ‘event study.’ Whereas an event study attempts to assess materiality quantitatively by analyzing stock price movements in response to disclosures that are alleged to be misleading or corrective, my approach analyzes the contemporaneous views of sell-side analysts in response to the disclosures that are alleged to be misleading or corrective.”  
**Fiorino Report, p. 10.**

**Dr. Fiorino’s Assumptions About Stock Return Significance Are Incorrect**

139. Despite having run no event study to properly analyze the empirical movements of the Pharmacia stock price, Dr. Fiorino draws conclusions about the empirical movements of the Pharmacia stock price.

“Furthermore, this finding of immateriality is supported by the lack of change in Pharmacia’s stock price as a result of the disclosure of the allegedly previously undisclosed CLASS results.”  
**Fiorino Report, p. 18.**

“Consistent with this finding that the allegedly previously undisclosed CLASS results were immaterial, the dissemination of these results had no impact on Pharmacia’s stock price (Figure 5). As reflected in Figure 5, Pharmacia stock closed just \$0.63 lower on February 6, 2001 than the prior day’s close.”  
***Ibid.*, p. 24.**

“In conclusion, I find that the results of the CLASS study undisclosed by the Defendants in April 2000 cannot be viewed as material (and consequently the cause of a falsely elevated stock price) because the full and widespread disclosure of those results on February 6, 2001 did not

result in changes to Pharmacia forward EPS estimates, Celebrex sales forecasts or the Celebrex prescription growth trend, ***nor was there a decline in Pharmacia's stock price.***"  
*Ibid.*, p. 26 (emphasis added).

"Moreover, the disclosure of those results was not associated with a decline in Pharmacia's stock price on February 6 and did not cause or contribute to the Pharmacia stock price decline on February 7, 2001 ..."  
*Ibid.*, p. 32.

"I noted earlier that there was no change in the stock price on February 6; on February 7, with the FDA Arthritis Advisory Committee voting against a Celebrex label change, Pharmacia's stock declined by 2.6%. In contrast, after the Advisory Committee voted in favor of a Vioxx label change on February 8, Pharmacia's stock ended the day down 5.6%."  
*Ibid.*, p. 33.

140. Because Dr. Fiorino fails to conduct the proper event study analysis, he draws incorrect conclusions about the magnitudes of Pharmacia residual returns and the factors that caused them. He contends that the February 6<sup>th</sup> disclosure caused no price movement, but he fails to consider the price change over the next two days as investors and analysts (including himself at the time<sup>22</sup>) processed the newly disclosed information. He fails to control for the market effect, peer group effect, and the effect of information on the value of the New Monsanto business (which he admits was important<sup>23</sup>). He fails to consider that the Pharmacia Pharmaceutical Stock Price fell a statistically significant 4.17%, 6.91%, and 11.81% on February 7<sup>th</sup>, February 8<sup>th</sup>, and over the three day window 6-8 February 2001, respectively.

#### **Dr. Fiorino Contradicts His Own Argument About What Moves Stock Prices**

141. Dr. Fiorino argues that the CLASS disclosures were not material and could not have caused the Pharmacia stock price decline because he contends analysts' forecasts of sales and earnings did not change after the disclosure.

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<sup>22</sup> "FDA Review of Celebrex More Negative Than Expected – Panel Could Be Controversial," by Carl Seiden, Roopesh Patel, Tony Fiorino, and Gloria Tsuen, JP Morgan, analysts report, 7 February 2001, JPMC 001610 - 13.

<sup>23</sup> Fiorino Report, p. 9.

“Therefore, if the Plaintiffs’ allegation regarding the materiality of the allegedly initially undisclosed CLASS results is correct, then upon learning of these results, analysts would have viewed the prospects for Celebrex as materially worse and would have lowered their Celebrex sales forecasts and reduced their Pharmacia EPS estimates. Furthermore, were these results material, their dissemination to physicians would have resulted in a change in Celebrex prescription trends. Yet as discussed below, there were no such changes. Therefore, I conclude that the results of the CLASS study undisclosed in April 2000 and subsequently disclosed in February 2001 cannot be considered material.”

**Fiorino Report, pp. 17-18.**

“The lack of adjustment in Celebrex sales forecasts and Pharmacia EPS estimates means that analysts did not find the allegedly previously undisclosed results to be material with regard to their expectations for Celebrex.”

***Ibid.*, p. 19.**

142. The earnings forecasts Dr. Fiorino presents compare forecasts before February 6<sup>th</sup> with forecasts made up to 12 February 2001.<sup>24</sup> Dr. Fiorino does not give the dates of the sales forecasts he presents in his Table 1, however my review of the analysts’ sales forecasts indicates that the “after” forecasts may be as late as May 2001. Consequently, analyst forecasts remained steady past February 8<sup>th</sup> and not just past February 6<sup>th</sup> as Dr. Fiorino suggests.
143. Surprisingly, while Dr. Fiorino argues that the steady forecasts rule out the information disclosed on February 6<sup>th</sup> as having been material and causative of a Pharmacia stock price decline, he concludes that the Advisory Committee’s announcement on February 8<sup>th</sup> pertaining to Vioxx, despite it too having no apparent impact on analysts’ reported sales and earnings forecasts, was material and responsible for a decline in the Pharmacia stock price.

“In contrast to the previous day’s results, at approximately 3:00 p.m. on February 8, 2001, the same advisory committee voted to recommend incorporation of new safety data from Merck’s VIGOR trial into the Vioxx label. A change for Vioxx but no change for Celebrex would put Celebrex at a competitive disadvantage, and this risk – which was completely unrelated to the allegedly initially undisclosed CLASS results

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<sup>24</sup> *Ibid.*, p. 18.



that had been disclosed in the Advisory Committee briefing documents on February 6 – caused a decline in Pharmacia’s stock price.”  
**Fiorino Report, pp. 32-33.**

“Specifically, Pharmacia’s stock price declined on February 7 because the FDA Arthritis Advisory Committee vote against a Celebrex label change, and Pharmacia’s stock price declined on February 8 because the same Committee voted in favor of a label change for Vioxx, Celebrex’s competitor.”  
***Ibid.*, pp. 27-28.**

144. Dr. Fiorino’s arguments are inconsistent and internally contradictory. If he believes that the Vioxx decision, though it caused no change in analysts’ earnings and sales forecasts, caused the Pharmacia stock price decline, then certainly he cannot argue that the CLASS disclosures were immaterial and caused no price decline on account of the same steady forecasts.

Dr. Fiorino’s Attribution of the Pharmacia Stock Price Decline to the Vioxx Announcement is Unsupported, Inconsistent, and Incorrect

145. Dr. Fiorino’s contention that the Vioxx announcement on February 8<sup>th</sup> caused the decline in Pharmacia’s stock price is not only unsupported, but runs contrary to his own opinion about what indicates materiality.
146. As noted, Dr. Fiorino argues that to be material, information must impact analysts’ sales and earnings forecasts. But, as Dr. Fiorino states on page 19 of his report, the Vioxx announcement did not change the Merck sales and earnings forecast of a “highly respected buy-side pharmaceuticals analyst.”

“In an internal note dated February 9, 2001, Norm Fidel, the highly respected buy-side pharmaceuticals analyst at Alliance, provides evidence of an identical process from one major institutional investor that managed portfolios for the Plaintiffs, noting the panel outcomes and writing ‘[t]here are *no changes to sales estimate [sic], earnings estimates or ratings* of the three companies’ (referring to Pharmacia, Pfizer and *Merck*).”  
**Fiorino Report, p. 19, footnote 20 (emphasis added).**

147. Moreover, Dr. Fiorino neglects to consider that the Vioxx announcement caused no significant movement in the Merck stock price, which according to Dr. Lehn, renders the news immaterial.

**Dr. Fiorino Disregards the Academic Literature on Reputation Effects**

148. Dr. Fiorino's premise that in order for a disclosure to be material it must change analysts' forecasts of sales and earnings is inaccurate and contradicted by abundant academic research. Published research has demonstrated that the impact of a corrective disclosure on management's reputation can have a significant negative effect on a company's stock price. For example:

"Risk/uncertainty likely increases and future prospects may well decrease when management integrity and competence are called into question.

...

This may be due to an increase in the discount rate because fraud creates uncertainty about the reliability and credibility of management representations, which increases the perceived information asymmetry between management and stockholders."

**"Determinants of Market Reactions to Restatement Announcements," by Zoe-Vonna Palmrose, *et al.*, *Journal of Accounting and Economics*, 2004, p. 63.**

"Our results show that reputation helps discipline financial misrepresentations – indeed, the evidence indicates that market-imposed reputation losses are of *primary* importance. One way to illustrate the importance of the reputation loss is to consider the average impact on a firm that inflates its market value by \$1 through deceptive financial reporting practices. When the deception is uncovered, the point estimates from Panel A of Table 9 indicate that the firm loses this dollar, *plus* an additional \$3.08 in expected legal penalties and lost reputation. (Since the readjustment effect equals 24.53% of the total dollar loss, a \$1.00 readjustment implies a total dollar loss of \$4.08 (= \$1.00/0.2453).) Of the additional loss, only \$0.36 represents the expectation of legal penalties. The remaining \$2.71 is the present value of the expected higher financing and contracting costs or reduced cash flows that result from the firm's misconduct. This is an empirical estimate of one portion of Jensen's (2005) agency cost of overvalued equity, namely, the reputational cost of cooking the books (and being apprehended).

Prior research indicates that reputation losses are important for some other types of corporate misconduct, including false advertising (Peltzman (1981)), product recalls (Jarrell and Peltzman (1985)), air safety disasters

(Mitchell and Maloney (1989)), frauds of private parties (Karpoff and Lott (1993), Alexander (1999), and Murphy, Shrieves, and Tibbs (2009)), investigations of IPO underwriters (Beatty, Bunsis, and Hand (1998)), and defense procurement fraud (Karpoff, Lee, and Vondrzyk (1999)).”  
“The Cost to Firms of Cooking the Books,” by Jonathan M. Karpoff, *et al.*, *Journal of Financial and Quantitative Analysis*, 2008, p. 601.

149. As the quotes above explain, the negative reputational effects of corporate misdeeds can reduce a company’s valuation by increasing risk and uncertainty, and raising financing costs. These factors are not necessarily reflected in analysts’ sales and earnings forecasts, contrary to Dr. Fiorino’s premise that only sales and earnings matter.
150. Additionally, Pharmacia considered reputation effects to be important. During a Pharmacia Board of Directors meeting, held on or about 25 September 2001, the Board discussed CLASS and the issue surrounding the 6-month versus 12-month data. This issue, according to Pharmacia’s CEO, Fred Hassan, was important enough to discuss with the Board of Directors because it “brought the integrity of the Company into question.”

“Q. And then the next bullet point says, ‘CLASS’. That’s referring to the CLASS trial that we’ve been discussing today?

A. Yes.

Q. And then next to that it says 6-month versus 12-month reporting?

A. Yes.

Q. And then under that it says ‘Integrity of company’?

A. Yes.

Q. And is it fair to say that you thought this was important enough to discuss with the board the 6-month versus 12-month issue in the middle 2001?

A. Yes.

Q. And you thought it was important because it brought the integrity of the company into question?

A. Yes.”

**Deposition Transcript of Fred Hassan, dated 22 February 2011, p. 217.**

151. Dr. Fiorino either ignores or is unaware of the vast academic literature on reputation effects.<sup>25</sup> He also ignores that Defendants concurred about the value of the Company's perceived integrity. Dr. Fiorino is wrong to contend that for purposes of valuing a company, only revenue and earnings matter.

**Dr. Fiorino's Opinions About Analyst Coverage and the Materiality of the CLASS Disclosure Are Belied by the Analyst Report He Coauthored**

152. Dr. Fiorino asserts that analysts generally only write reports about material news. He also contends that the CLASS disclosure on February 6<sup>th</sup> was immaterial.

"First, analysts infrequently publish reports or change estimates based on immaterial news ... ."  
**Fiorino Report, p. 11.**

"In conclusion, I find that the results of the CLASS study undisclosed by the Defendants in April 2000 cannot be viewed as material (and consequently the cause of a falsely elevated stock price) ... ."  
***Ibid.*, p. 26.**

153. However, as a member of JPMorgan's analyst team covering Pharmacia, on 7 February 2001, Dr. Fiorino coauthored a report titled, "FDA Review of Celebrex More Negative Than Expected – Panel Could Be Controversial." In this analyst report, Dr. Fiorino and his team analyzed and disseminated the corrective information posted on the FDA website. As

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<sup>25</sup> In *Corporate Finance: Creating Value While Doing Right*, 2005, authors Jonathan M. Karpoff, Timothy J. Gallagher, and Joseph D. Andrew review this literature and cite to the following articles which analyze and quantify the valuation effects of management reputation: Cindy R. Alexander, "On the Nature of the Reputational Penalty for Corporate Crime: Evidence," *Journal of Law and Economics* 42, 1999, p. 489 (for frauds of related parties) (see also Alan K. Reichert, Michael Lockett, and Ramesh P. Rao, "The Impact of Illegal Business Practice on Shareholder Returns," *The Financial Review*, 1996, pp. 67-85; and J.L. Strachan, D.B. Smith, and W.L. Beedles, "The Price Reaction to (Alleged) Corporate Crime," *The Financial Review* 18, 1983, pp. 121-132); Sam Peltzman, "The Effects of FTC Advertising Regulation," *Journal of Law and Economics* 24, 1981, p. 403 (for product recalls); Jonathan M. Karpoff, D. Scott Lee, and Valaria Vondryk, "Defense Procurement Fraud, Penalties, and Contractor Influence," *Journal of Political Economy* 107, 1999, p. 809 (for defense procurement frauds); Terrance R. Skantz, Dale O. Cloninger, and Thomas H. Strickland, "Price-Fixing and Shareholder Returns," *The Financial Review* 1, 1990, p. 153 (for price fixing); Deborah L. Murphy, Ronald E. Shrieves, and Samuel L. Tibbs, "Determinants of the Stock Price Reaction to Allegations of Corporate Misconduct: Earnings, Risk, and Firm Size Effects," University of Tennessee working paper (for bribery); Jonathan M. Karpoff and John R. Lott, Jr., "On the Determinants and Importance of Punitive Damages Awards," *Journal of Law and Economics* 62, 1999, p. 527 (for punitive damage lawsuits); Jonathan M. Karpoff, John R. Lott, Jr., and Eric Wehrly, "The Reputational Penalties for Environmental Violations: Empirical Evidence," *Journal of Law and Economics*, 2005; and Kari Jones and Paul H. Rubin, "Effects of Harmful Environmental Events on Reputations of Firms," *Advances in Financial Economics*, Volume VI, ed. by Mark Hirschey, Kose John, and Anil Makhija, 2001, pp. 161-182 (for environmental violations).

the report title indicates, Dr. Fiorino and his team viewed the posted reports and CLASS data to be unexpected, contrary to prior information, and negative. Clearly then, Dr. Fiorino believed the news to be material.

154. To be consistent with his current opinion about what news analysts cover, Dr. Fiorino should still conclude the February 6<sup>th</sup> corrective disclosure was material.

Dr. Fiorino and His Team Did Not Issue Another Analyst Report Covering the Subsequent FDA Committee Announcements

155. Not only does Dr. Fiorino assert that analysts rarely publish about immaterial events, but he also states that they do publish when new material information emerges.

“First, analysts infrequently publish reports or change estimates based on immaterial news, but *almost always publish reports or notes on events they deem relevant or material to investors ...*”  
Fiorino Report, p. 11 (emphasis added).

156. In the report he submitted for this case, Dr. Fiorino contends that the FDA Advisory Committee decisions about Celebrex and Vioxx, on February 7<sup>th</sup> and 8<sup>th</sup> respectively, were intervening events and responsible for Pharmacia stock price declines. However, Dr. Fiorino’s JPMorgan report published on February 7<sup>th</sup> (which covered the posting of the reviewer reports containing the negative CLASS data) was issued prior to the FDA Advisory Committee meeting that day. His team did not issue another report covering the February 7<sup>th</sup> Advisory Committee meeting or the February 8<sup>th</sup> Vioxx announcement. Apparently, at the time, Dr. Fiorino did not assess these follow-on events to be material.

Dr. Fiorino’s Opinion About the Speed of Price Adjustment is Belied by His Own Analyst Report

157. Dr. Fiorino argues that the February 7<sup>th</sup> stock price decline was not caused by the disclosure that began on February 6<sup>th</sup>, because it is his opinion that stock price reactions are always fully completed within a few hours of an announcement. He bases his opinion not on published research or rigorous analysis, but rather on his unverifiable and unreplicable personal experiences.

“Based on my experience as a sell-side analyst and as an investor in pharmaceutical and biotechnology stocks, any contention by Plaintiffs that the stock price decline on February 7, 2001 can be associated with the disclosure of the full CLASS data because the market did not fully appreciate or incorporate the data disclosed on February 6 until sometime during the trading day on February 7, must be rejected out-of-hand. Contrary to such a contention, it takes minutes, at most a few hours, for data from Advisory Committee briefing documents to be incorporated into stock prices.”

**Fiorino Report, pp. 30-31.**

158. This opinion too is contradicted by Dr. Fiorino’s analyst report publication record. While Dr. Fiorino contends the FDA reviewer reports were posted on 6 February 2001, he and his team did not publish their report covering this event until the next day. If analysts play any useful role in analyzing and disseminating information (another opinion held by Dr. Fiorino<sup>26</sup>), then the timing of his own report covering the February 6<sup>th</sup> corrective disclosure indicates that the process takes longer than a few hours.

Dr. Fiorino’s Analyst Report Illustrates That the February 6<sup>th</sup> Disclosure Was Complex and Confounded

159. Dr. Fiorino argues, without any rigorous analysis or citation to authoritative literature, that the Pharmacia stock price decline over the three days, 6-8 February 2001, was not caused by the corrective disclosure that began on 6 February 2001.

“As discussed in greater detail below, there is absolutely no basis to claim that a stock price decline after February 6, 2001 had any causal relation to the disclosure of the full CLASS data.”

**Fiorino Report, p. 27.**

160. Dr. Fiorino arrives at this incorrect conclusion because he disregards that the information disclosed on February 6<sup>th</sup> was complex and confounded by the Company’s briefing document.
161. As noted in my original report, the academic literature explains that price reactions to complex and unexpected announcements may be protracted.

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<sup>26</sup> “Second, sell-side pharmaceutical analysts are highly focused on the industry and are relied upon by their clients, investors of varying capacities, to apply their industry knowledge and expertise in quickly addressing the financial implications of new developments regarding important drugs for the companies developing or marketing those drugs.” Fiorino Report, p. 11.

162. That the CLASS disclosures fit this description is undeniable, and evident even in the analyst report Dr. Fiorino and his team published on February 7<sup>th</sup>. That report described the new information as being contrary to prior expectations, and described the statistical analysis of the CLASS data to be “thornier than we initially thought.”
163. Also, the report reflected Defendants’ countervailing obfuscation, as the report related Defendants’ “informed censoring” argument and presented the issue as an unsettled debate.

“Often the FDA review of data is gloomier than the Advisory Committee dialogue (to occur later today), so we will have to wait for the meetings today and tomorrow (for Vioxx) to get clear punchlines.”

**“Celebrex CLASS Trial Confirms GI Safety (With Slight Wrinkle) – No Cardiovascular Risk,” by Carl Seiden, Roopesh Patel, Tony Fiorino, and Gloria Tsuen, JP Morgan, analyst report, 17 April 2000, p. 2, Exhibit 17.**

“Pharmacia’s rationale for looking at the 26 week data only was that the greater withdrawal of patients from the diclofenac arm ‘censored’ later events (i.e., patients on diclofenac were more likely to develop symptoms and thus were disproportionately removed from the trial before having a chance to develop a serious upper GI events.)”  
*Ibid.*, p. 3.

164. Had there been full disclosure of the CLASS data with no obfuscation, the artificial inflation in the Pharmacia stock price may have dissipated more rapidly. But given the complexity of the data, coupled with Defendants’ countervailing representations, which were reflected in Dr. Fiorino’s analyst report, the process took three days.
165. On February 6<sup>th</sup>, the full CLASS data was posted, but were complex and accompanied by countervailing obfuscation. On February 7<sup>th</sup>, analysts and investors continued to analyze the data and were aided by the clarification provided by the FDA Advisory Committee’s deliberations. Analyst reports published on February 7<sup>th</sup>, including Dr. Fiorino’s, facilitated the market’s digestion of the new information. The price revaluation process continued visibly on February 8<sup>th</sup> as additional analyst reports were published. Observable facts prove that the market’s revaluation of Pharmacia stock in response to the CLASS disclosures took three days, from 6 February to 8 February 2001.
166. Dr. Fiorino’s contention that this and all price reactions must be instantaneous is baseless, and contrary to financial principals and the observable facts in this case.

**Dr. Fiorino's Attempt to Attribute the Price Decline to Other Events is Misguided**

167. Dr. Fiorino contends that numerous issues unrelated to Celebrex caused Pharmacia's stock price to decline.

“Investors had significant concerns over a number of non-Celebrex components of Pharmacia's business during and after the Class Period, clouding any attempt to attribute a declining stock price over time to any single cause.”

**Fiorino Report, p. 7.**

168. On pages 66-67 of his report, Dr. Fiorino lists the other events and issues he contends contributed to the stock price decline. These events and issues included tightening EPS guidance, Xalatan competition, competition with Ditropan XL, volatility in the Monsanto agriculture business, “lost revenues from the reversion of marketing rights to Ambien back to Sanofi in 2002,” among others.
169. None of these issues emerged during the 6-8 February 2001 window when the Pharmacia stock price declined due to the corrective disclosures about Celebrex. In fact, Dr. Fiorino admits that these issues arose subsequently.

“Thus, multiple new risks to Pharmacia's business came to the market's attention after the fourth quarter/full year 2000 earnings report ... .”

**Fiorino Report, p. 67.**

170. The Q4 2000 earnings announcement was made on 12 February 2001. That Dr. Fiorino attempts to attribute the price reaction over the three days following the CLASS corrective disclosure to numerous issues and events that occurred a week later underscores the weakness in his analysis stemming from his lack of legitimate stock return attribution methodology.



**Dr. Fiorino's Intraday Analysis is Improperly Selective and Factually and Methodologically Flawed**

171. Dr. Fiorino concludes that the Pharmacia stock price decline on 8 February 2001 “cannot reasonably be attributed to anything other than” the FDA Advisory Committee announcement about Vioxx.

“The intraday chart (Figure 7) clearly demonstrates that the drop in Pharmacia’s stock price began within minutes of the Advisory Committee’s recommendation to grant a label change for Vioxx, accompanied by a large surge in the trading volume of Pharmacia’s stock. This sharp decline on escalating volume cannot reasonably be attributed to anything other than the immediately preceding event, which was the FDA Arthritis Advisory Committee vote to recommend a Vioxx label change, which the market perceived as potentially detrimental to Celebrex’s sales.

...

**Fiorino Report, p. 33.**

**Factual Errors in Dr. Fiorino's Analysis of Intraday Prices On 8 February 2001**

172. Dr. Fiorino’s conclusion rests on factually flawed analysis. As described above, (similar to the factual errors contained in the Lehn Report) Dr. Fiorino uses the wrong time and prices to measure the decline immediately following the announcement. *Bloomberg* carried an *Associated Press* report of the Advisory Committee’s decision at 12:51 p.m., more than two hours before the 3:06 p.m. time at which Dr. Fiorino places the announcement. As shown in Exhibit-8, the announcement at 12:51 p.m. was followed immediately by an increase in the price of Pharmacia stock, not a decrease.
173. Similarly, Dr. Fiorino neglects to analyze movements that occurred in the price of Pharmacia stock prior to 3:00 p.m., and thus fails to observe that Pharmacia stock declined from the closing price of \$56.13 per share on 7 February 2001 to \$54.30 per share by 10:40 a.m. on 8 February 2001, indisputably before the Vioxx announcement. From the prior day’s close to this mid-morning point, the price declined \$1.83 per share, or 3.3%, which amounted to 58.5% of the total decline for the day.
174. Dr. Fiorino fails to consider the stock price slide in morning trading on February 8<sup>th</sup>, which appears to be a continuation of the previous day’s reaction to the corrective disclosure.

Methodological Errors in Dr. Fiorino's Intraday Analysis

175. Dr. Fiorino's intraday analysis is riddled with methodological errors and oversights. The following is a list of the errors that render Dr. Fiorino's conclusions unreliable:

- i. Failure to control for market and peer group effects;
- ii. Failure to control for information affecting Pharmacia's chemical and agricultural business (which he stated was an important factor);
- iii. Failure to consider the statistical problems arising from noise in intraday data that are well documented in the literature; and
- iv. Failure to conduct the specialized testing required when working with intraday data.

Dr. Fiorino Fails to Consider Pharmacia Stock's Intraday Price Movement On 7 February 2001

176. On page 24 of his report, Dr. Fiorino examines intraday prices on February 6<sup>th</sup>. While Dr. Fiorino examines intraday pricing data on both February 6<sup>th</sup> and 8<sup>th</sup>, he chooses not to examine the intraday data on February 7<sup>th</sup>. Had he applied the same analysis on the February 7<sup>th</sup> data that he applies to the February 6<sup>th</sup> and 8<sup>th</sup> data (which I do not accept as reliable nevertheless), he would have noticed that the declines in Pharmacia Pharmaceuticals and Pharmacia stock occurred prior to the Advisory Committee's 2:25 p.m. decision regarding Celebrex, undermining his conclusion that the Committee announcement was responsible for the day's stock price decline.
177. While Dr. Fiorino embraces intraday price analysis for his purposes of arguing that the February 8<sup>th</sup> price declines were caused by Merck news, and that there was no stock price reaction to the news on February 6<sup>th</sup>, he fails to apply that same analysis to February 7<sup>th</sup>, when such analysis would contradict his stated loss causation opinion.

**Dr. Fiorino's Representations of Select Investment Manager Recollections is Unscientific and Irrelevant**

178. On pages 70 through 74 of his report, Dr. Fiorino relates the deposition testimony given by four individuals who worked for "Plaintiffs' money managers." Dr. Fiorino represents that these individuals share his opinion about the immateriality of the CLASS disclosures.

"I have reviewed the deposition transcripts of those individuals and was not surprised to find that the Plaintiffs' own investment managers share

what this report has found to have been the market's perspective on the COX-2 inhibitors.”  
**Fiorino Report, p. 70.**

179. There are at least two major flaws in Dr. Fiorino's argument pertaining to the testimony of these particular investment managers. First, Dr. Fiorino appears to have misinterpreted what they said. Second, Dr. Fiorino fails to appreciate the generally accepted financial principal that the market comprises and aggregates a wide range of often divergent views. Whereas rigorous event study analysis, which Dr. Fiorino eschews, scientifically gauges the materiality of information to the market as a whole, unscientific anecdotal sampling, which Dr. Fiorino relies upon, does not.

Dr. Fiorino Misinterprets the Investment Professionals' Testimony

180. While Dr. Fiorino contends that the excerpted testimony from the select individuals he cites support his contention that the CLASS data disclosure was immaterial, none of the investment professionals said that.
181. In fact, the quote from Jane Davenport's testimony that Dr. Fiorino presents on page 72 of his report specifically links the Pharmacia stock price decline to Celebrex not receiving the label modification, which was the inevitable fallout from the disclosed data. As discussed above, the full CLASS data was responsible for the Advisory Committee not recommending the label change.

““The stock has sold off recently, probably due mainly to the FDA advisory committee's recommendations suggesting that the new label for Celebrex will not be as advantageous as some have hoped.””  
**Fiorino Report, p. 72, citing Deposition of Davenport, dated 27 June 2006, pp. 61-62.**

The Market Aggregates Disparate Views

182. Moreover, Dr. Fiorino's reliance on statements from select individuals relating their recollections of their prior opinions cannot substitute for the rigorous analysis of market data that he does not conduct.
183. It is a fundamental and generally accepted financial economic principle that the market accommodates diversity of opinion and information, and aggregates divergent opinions

into a consensus price. A finance textbook co-authored by Economics Nobel Prize winner Robert Merton explains the concept thusly.

“To see how the current market price of the stock is determined, we look at the aggregation of all analysts’ estimates, and assume that on average the market is in equilibrium (i.e. on average, the price will be such that the total (desired) demand equals total supply. ... Hence, the market price of the stock will reflect a weighted average of the opinions of all analysts.”  
*Finance*, by Zvi Bodie and Robert Merton, Prentice Hall, 2000, pp. 206-207.

184. There will always be individual market participants who do not share exactly the consensus view. This fact is precisely why it is necessary to apply rigorous scientific analysis to gauge market opinion (*e.g.* event study analysis) rather than relying primarily on the expressed opinions of unscientifically selected individuals. This fact is precisely why Dr. Fiorino’s approach is unreliable.

#### **LIMITING FACTORS**

185. This report is furnished solely for the purpose of court proceedings in the above named matter and may not be used or referred to for any other purpose. The analysis and opinions contained in this report are based on information available as of the date of this report. I reserve the right to supplement or amend this report, including in the event additional information becomes available.



Steven P. Feinstein, Ph.D., CFA

**Documents and Other Information Reviewed and Relied Upon in Addition to  
Documents Cited in the Feinstein June Report**

**EXPERT REPORTS**

- Expert Report of Dr. Kenneth M. Lehn, dated 7 June 2011.
- Expert Report of Dr. Michael Fiorino, dated 7 June 2011.

**NEWS ARTICLES / PRESS RELEASES**

- “Merck’s Financial Health Hinges on Sales of Its New Arthritis Pill,” by Robert Langreth, *Dow Jones Business News*, 14 April 1999.
- “FOCUS-FDA Panel backs Merck’s Vioxx Painkiller,” by Lisa Richwine, *Reuters News*, 21 April 1999.
- “The Cure: With Big Drugs Dying, Merck Didn’t Merge – It Found New Ones – Some Inspired Research, Aided By a Bit of Luck, Saves Company’s Independence –The Path to a Novel Painkiller,” by Gardiner Harris, *Wall Street Journal*, 10 January 2001.
- “Scientists Advise on New Drug Vioxx,” *Associated Press Wire*, 8 February 2001.

**ANALYST REPORTS**

- “MRK’s: VIOXX GI Outcomes Data – Details Part 1,” by Christina Heuer and Mark Striker, Salomon Smith Barney, Merck analyst report, 28 March 2000.
- “Celebrex CLASS Trial Confirms GI Safety (With Slight Wrinkle) – No Cardiovascular Risk,” by Carl Seiden, *et al.*, JP Morgan, analyst report, 17 April 2000, Exhibit 17.
- “Much Ado About Nothing!!! Fundamentals on Track, Stock Weakness Creates Buying Opportunity,” by Barbara A. Ryan, *et al.*, Deutsche Banc Alex. Brown, Merck analyst report 29 January 2001.
- “FDA Review Of Celebrex More Negative Than Expected Panel Could Be Controversial,” by Carl Seiden, *et al.*, J.P. Morgan Securities, Pharmacia analyst report 7 February 2001, [JPMC 001610-12].
- “FDA Unlikely to Improve Celebrex Label,” by Joseph P. Riccardo, *et al.*, Bear Stearns, Pharmacia analyst report, 7 February 2001, [DEFEX 008229-31].
- “PHA: FDA Reviews Celebrex & Vioxx Safety Data,” by Mark Striker and George Grofik, Salomon Smith Barney, Pharmacia analyst report, 7 February 2001.
- “Pharmaceuticals: Disappointing FDA Review of GI Safety Data for Celebrex,” by Jeffrey Chaffkin, *et al.*, UBS Warburg, Pharmacia analyst report, 8 February 2001 [DEFEX 009148].

**Documents and Other Information Reviewed and Relied Upon in Addition to  
Documents Cited in the Feinstein June Report**

- “Initiating Coverage: Vioxx Withdrawal Could Present An Opportunity,” by Jon Lecroy, M.D., *et al.*, Natexis Bleichroeder, Merck analyst report, 1 October 2004.

**SEC FILINGS**

- Merck & Co., Inc. Form DEF 14A, filed 22 March 2001.
- Merck & Co., Inc. Form 10-K for the Fiscal year Ended 31 December 2003, filed 10 March 2004.

**ACADEMIC AND PROFESSIONAL LITERATURE**

- Aït-Sahalia, Yacine, Jianqing Fan, and Dacheng Xiu, “High-Frequency Covariance Estimates With Noisy and Asynchronous Financial Data,” *Journal of the American Statistical Association*, December 2010.
- Barclay, Michael J., and Robert H. Litzenberger, “Announcement Effects of New Equity Issues and The Use of Intraday Price Data,” *Journal of Financial Economics*, 1988.
- Bodie, Zvi and Robert Merton, *Finance*, Prentice Hall, 2000.
- Brealey, Richard A., and Stewart C. Myers, *Principles of Corporate Finance*, 7<sup>th</sup> edition, McGraw-Hill Irwin, 2007.
- Karpoff, Jonathan M., Timothy J. Gallagher, and Joseph D. Andrew, Chapter 2 of *Corporate Finance: Creating Value While Doing Right*, 2005.
- Karpoff, Jonathan M., D. Scott Lee, and Gerald S. Martin, “The Cost to Firms of Cooking the Books,” *Journal of Financial and Quantitative Analysis*, 2008.
- Lehn, Kenneth M., and Mengxin Zhao, “CEO Turnover after Acquisitions: Are Bad Bidders Fired?” *Journal of Finance*, August 2006.
- Mucklow, Belinda, “Market Microstructure: Effects on Intraday Event Studies,” *Contemporary Accounting Research*, Spring 1994.
- Palmrose, Zoe-Vonna, Vernon J. Richardson and Susan Scholz, *Journal of Accounting and Economics*, 2004.
- Shanken, Jay, “A Bayesian Approach to Testing Portfolio Efficiency,” *Journal of Financial Economics*, 1987.

**DATA AND DATABASES**

- TAQ (Trade and Quote) database

**Exhibit-1**

**Documents and Other Information Reviewed and Relied Upon in Addition to  
Documents Cited in the Feinstein June Report**

**COMPANY DOCUMENTS**

- Internal Email, dated 1 February 2001, Exhibit 352, [DEFS 00280719 – 30].
- Company Presentation, Exhibit-391, [DEFS 04133602 – 39].
- Internal Memorandum, Exhibit 125 [DEFS 02524647 – 61].
- Internal Emails, dated 16-17 April 2000, Exhibit 414, [DEFS 00122679 – DEFS 00122680].
- Internal Memorandum, “Label Review Meeting,” dated 27 April 2000, Exhibit 130 [DEFS 01433613].
- Deposition Transcript of Erick J. Lucera, 19 June 2006.
- Deposition Transcript of Jane Davenport, 27 June 2006.
- Deposition Transcript of Jeff Silverman, 27 June 2006.
- Deposition Transcript of David Thompson, 29 June 2006.
- Deposition Transcript of Fred Hassan, dated 22 February 2011.

**OTHER**

- Any other documents and data cited in the report.

**Exhibit-2**

**Steven P. Feinstein, Ph.D., CFA**  
**Testimony Provided Since June Report**

In Re Constar International Inc. Securities Litigation  
United States District Court  
Eastern District of Pennsylvania  
Civil Action No. 2:03-cv-05020-EL  
Deposition Testimony  
June 2011



### Exhibit-3

## Replication of Dr. Lehn's Pharmacia Regression Using Logarithmic Returns

Estimation Period: 17 April 2000 to 6 August 2001

Regression Statistics			
Multiple R		0.430	
Adjusted R Square		0.335	
Standard Error		1.93%	
Observations		329	
F-Statistic		4.512	
F-Statistic Significance Level		~0%	

	Coefficients	Standard Error	<i>t</i> -statistic
Intercept	-0.09%	0.11%	-0.82
NYSE Index	0.183	0.117	-1.537
Dr. Lehn Peer Index	0.907	0.088	10.323
17 April 2000	-0.40%	1.94%	-0.204
18 April 2000	-3.85%	1.95%	-1.973
24 April 2000	-1.74%	1.93%	-0.899
25 April 2000	-8.27%	1.95%	-4.239
26 April 2000	-0.58%	1.94%	-0.300
1 May 2000	-0.60%	1.93%	-0.311
2 May 2000	1.30%	1.93%	0.671
3 May 2000	3.85%	1.95%	1.977
19 May 2000	3.88%	1.94%	1.995
22 May 2000	-2.74%	1.93%	-1.420
23 May 2000	0.88%	1.93%	0.457
24 May 2000	-4.23%	1.93%	-2.189
8 June 2000	-0.22%	1.93%	-0.111

### Exhibit-3

#### Replication of Dr. Lehn's Pharmacia Regression Using Logarithmic Returns

Estimation Period: 17 April 2000 to 6 August 2001

9 June 2000	3.81%	1.93%	1.972
12 June 2000	0.17%	1.93%	0.086
24 July 2000	-0.19%	1.94%	-0.100
25 July 2000	6.67%	1.93%	3.451
26 July 2000	1.68%	1.94%	0.868
12 September 2000	-1.06%	1.93%	-0.546
13 September 2000	0.85%	1.93%	0.442
14 September 2000	-0.88%	1.93%	-0.456
15 September 2000	-0.22%	1.93%	-0.116
18 September 2000	-1.84%	1.94%	-0.949
19 September 2000	1.29%	1.93%	0.669
27 October 2000	-1.87%	1.94%	-0.965
30 October 2000	-5.24%	1.95%	-2.693
31 October 2000	5.08%	1.95%	2.609
1 November 2000	4.19%	1.93%	2.171
5 February 2001	0.89%	1.93%	0.459
6 February 2001	-0.19%	1.93%	-0.096
7 February 2001	-2.92%	1.93%	-1.513
9 February 2001	1.77%	1.93%	0.914
12 February 2001	-0.63%	1.94%	-0.323
13 February 2001	-3.39%	1.93%	-1.752
24 April 2001	0.18%	1.93%	0.092
25 April 2001	-0.02%	1.94%	-0.013
26 April 2001	3.82%	1.93%	1.975
29 May 2001	-1.63%	1.93%	-0.843
30 May 2001	1.04%	1.93%	0.535
31 May 2001	0.91%	1.93%	0.469

**Exhibit-3**

**Replication of Dr. Lehn's Pharmacia Regression Using Logarithmic Returns**

Estimation Period: 17 April 2000 to 6 August 2001

24 July 2001	-1.60%	1.94%	-0.825
25 July 2001	-0.28%	1.94%	-0.142
26 July 2001	-1.64%	1.93%	-0.846
3 August 2001	0.80%	1.93%	0.413
6 August 2001	0.98%	1.93%	0.508

**Exhibit-4**

**Replication of Dr. Lehn's Event Study Using Logarithmic Returns**

**Pharmacia Corporation**

<b>Date</b>	<b>PHA Logarithmic Return</b>	<b>NYSE Index Logarithmic Return</b>	<b>Dr. Lehn's Peer Index Logarithmic Return</b>	<b>PHA Explained Return</b>	<b>PHA Residual Return</b>	<b><i>t</i>-statistic</b>	<b>p-value 1-tail</b>	<b>p-value 2-tail</b>	<b>Statistically Significant</b>
17 April 2000	1.86%	1.42%	2.31%	2.26%	-0.40%	-0.21	41.85%	83.70%	No
18 April 2000	-1.98%	2.33%	1.69%	1.86%	-3.85%	-2.00	2.35%	4.70%	Yes
19 April 2000	11.87%	-0.24%	-1.28%	-1.30%	13.17%	6.83	0.00%	0.00%	Yes
17-19 April 2000	11.75%	3.50%	2.73%	2.83%	8.92%	2.67	0.40%	0.79%	Yes

**Exhibit-5**

**Merck & Co., Inc.**

**Common Stock Prices, Dividends and Returns**

<b>Date</b>	<b>MRK Closing Stock Price</b>	<b>MRK Dividend</b>	<b>MRK Logarithmic Return</b>
10/18/2000	\$78.19		
10/19/2000	\$77.56		-0.80%
10/20/2000	\$81.88		5.41%
10/23/2000	\$84.75		3.45%
10/24/2000	\$85.44		0.81%
10/25/2000	\$87.31		2.17%
10/26/2000	\$86.69		-0.72%
10/27/2000	\$88.00		1.50%
10/30/2000	\$88.69		0.78%
10/31/2000	\$89.94		1.40%
11/1/2000	\$89.75		-0.21%
11/2/2000	\$89.13		-0.70%
11/3/2000	\$87.88		-1.41%
11/6/2000	\$90.00		2.39%
11/7/2000	\$86.88		-3.53%
11/8/2000	\$90.81		4.43%
11/9/2000	\$90.44		-0.41%
11/10/2000	\$91.50		1.17%
11/13/2000	\$89.38		-2.35%
11/14/2000	\$91.06		1.87%
11/15/2000	\$91.63		0.62%
11/16/2000	\$90.19		-1.58%
11/17/2000	\$88.50		-1.89%
11/20/2000	\$90.38		2.10%
11/21/2000	\$92.00		1.78%
11/22/2000	\$90.69		-1.44%
11/24/2000	\$89.44		-1.39%
11/27/2000	\$91.63		2.42%
11/28/2000	\$92.63		1.09%
11/29/2000	\$94.88		2.40%
11/30/2000	\$92.69		-2.33%
12/1/2000	\$90.63		-2.25%
12/4/2000	\$91.94		1.44%
12/5/2000	\$90.00		-2.13%
12/6/2000	\$89.56	\$0.34	-0.11%
12/7/2000	\$91.06		1.66%
12/8/2000	\$89.56		-1.66%

**Exhibit-5**

**Merck & Co., Inc.**

**Common Stock Prices, Dividends and Returns**

<b>Date</b>	<b>MRK Closing Stock Price</b>	<b>MRK Dividend</b>	<b>MRK Logarithmic Return</b>
12/11/2000	\$90.63		1.18%
12/12/2000	\$91.38		0.82%
12/13/2000	\$92.00		0.68%
12/14/2000	\$91.00		-1.09%
12/15/2000	\$90.38		-0.69%
12/18/2000	\$89.31		-1.18%
12/19/2000	\$91.50		2.42%
12/20/2000	\$93.38		2.03%
12/21/2000	\$92.50		-0.94%
12/22/2000	\$90.50		-2.19%
12/26/2000	\$92.69		2.39%
12/27/2000	\$92.69		0.00%
12/28/2000	\$94.75		2.20%
12/29/2000	\$93.63		-1.19%
1/2/2001	\$93.00		-0.67%
1/3/2001	\$89.13		-4.26%
1/4/2001	\$85.00		-4.74%
1/5/2001	\$83.31		-2.01%
1/8/2001	\$83.50		0.22%
1/9/2001	\$84.00		0.60%
1/10/2001	\$83.19		-0.97%
1/11/2001	\$81.63		-1.90%
1/12/2001	\$81.44		-0.23%
1/16/2001	\$83.31		2.28%
1/17/2001	\$81.25		-2.51%
1/18/2001	\$82.88		1.98%
1/19/2001	\$82.44		-0.53%
1/22/2001	\$82.31		-0.15%
1/23/2001	\$79.56		-3.40%
1/24/2001	\$78.94		-0.79%
1/25/2001	\$81.88		3.65%
1/26/2001	\$82.25		0.46%
1/29/2001	\$80.31		-2.39%
1/30/2001	\$81.00		0.86%
1/31/2001	\$82.18		1.45%
2/1/2001	\$84.48		2.76%
2/2/2001	\$83.97		-0.61%

**Exhibit-5**

**Merck & Co., Inc.**

**Common Stock Prices, Dividends and Returns**

<b>Date</b>	<b>MRK Closing Stock Price</b>	<b>MRK Dividend</b>	<b>MRK Logarithmic Return</b>
2/5/2001	\$84.48		0.61%
2/6/2001	\$84.36		-0.14%
2/7/2001	\$81.85		-3.02%
2/8/2001	\$82.97		1.36%
2/9/2001	\$82.72		-0.30%
2/12/2001	\$82.98		0.31%
2/13/2001	\$80.75		-2.72%
2/14/2001	\$79.63		-1.40%
2/15/2001	\$78.10		-1.94%
2/16/2001	\$77.29		-1.04%
2/20/2001	\$77.90		0.79%
2/21/2001	\$78.71		1.03%
2/22/2001	\$77.70		-1.29%
2/23/2001	\$77.08		-0.80%
2/26/2001	\$79.33		2.88%
2/27/2001	\$79.91		0.73%
2/28/2001	\$80.20		0.36%
3/1/2001	\$79.75		-0.56%
3/2/2001	\$80.15		0.50%
3/5/2001	\$79.53		-0.78%
3/6/2001	\$77.45		-2.65%
3/7/2001	\$74.40	\$0.34	-3.56%
3/8/2001	\$74.79		0.52%
3/9/2001	\$75.69		1.20%
3/12/2001	\$74.15		-2.06%
3/13/2001	\$72.93		-1.66%
3/14/2001	\$71.93		-1.38%
3/15/2001	\$74.05		2.90%
3/16/2001	\$71.45		-3.57%
3/19/2001	\$72.07		0.86%
3/20/2001	\$70.25		-2.56%
3/21/2001	\$67.96		-3.31%
3/22/2001	\$69.71		2.54%
3/23/2001	\$68.98		-1.05%
3/26/2001	\$71.48		3.56%
3/27/2001	\$73.61		2.94%
3/28/2001	\$75.15		2.07%

**Exhibit-5**

**Merck & Co., Inc.**

**Common Stock Prices, Dividends and Returns**

<b>Date</b>	<b>MRK Closing Stock Price</b>	<b>MRK Dividend</b>	<b>MRK Logarithmic Return</b>
3/29/2001	\$74.20		-1.27%
3/30/2001	\$75.90		2.27%
4/2/2001	\$74.25		-2.20%
4/3/2001	\$72.81		-1.96%
4/4/2001	\$74.48		2.27%
4/5/2001	\$75.78		1.73%
4/6/2001	\$76.42		0.84%
4/9/2001	\$78.00		2.05%
4/10/2001	\$78.39		0.50%
4/11/2001	\$77.15		-1.59%
4/12/2001	\$79.50		3.00%
4/16/2001	\$79.10		-0.50%
4/17/2001	\$80.85		2.19%
4/18/2001	\$79.30		-1.94%
4/19/2001	\$78.27		-1.31%
4/20/2001	\$73.61		-6.14%
4/23/2001	\$74.25		0.87%
4/24/2001	\$73.46		-1.07%
4/25/2001	\$74.86		1.89%
4/26/2001	\$74.85		-0.01%
4/27/2001	\$75.65		1.06%
4/30/2001	\$75.97		0.42%
5/1/2001	\$75.60		-0.49%
5/2/2001	\$74.91		-0.92%
5/3/2001	\$75.27		0.48%
5/4/2001	\$76.37		1.45%
5/7/2001	\$76.90		0.69%
5/8/2001	\$76.44		-0.60%
5/9/2001	\$77.32		1.14%
5/10/2001	\$76.52		-1.04%
5/11/2001	\$75.94		-0.76%
5/14/2001	\$76.69		0.98%
5/15/2001	\$75.90		-1.04%
5/16/2001	\$78.10		2.86%
5/17/2001	\$78.60		0.64%
5/18/2001	\$77.40		-1.54%
5/21/2001	\$77.40		0.00%



**Exhibit-5**

**Merck & Co., Inc.**

**Common Stock Prices, Dividends and Returns**

<b>Date</b>	<b>MRK Closing Stock Price</b>	<b>MRK Dividend</b>	<b>MRK Logarithmic Return</b>
5/22/2001	\$75.10		-3.02%
5/23/2001	\$74.00		-1.48%
5/24/2001	\$72.50		-2.05%
5/25/2001	\$72.60		0.14%
5/29/2001	\$74.39		2.44%
5/30/2001	\$73.28		-1.50%
5/31/2001	\$72.99	\$0.34	0.07%
6/1/2001	\$74.20		1.64%
6/4/2001	\$74.32		0.16%
6/5/2001	\$75.33		1.35%
6/6/2001	\$73.95		-1.85%
6/7/2001	\$74.81		1.16%
6/8/2001	\$74.22		-0.79%
6/11/2001	\$72.25		-2.69%
6/12/2001	\$72.61		0.50%
6/13/2001	\$73.13		0.71%
6/14/2001	\$73.90		1.05%
6/15/2001	\$73.75		-0.20%
6/18/2001	\$74.25		0.68%
6/19/2001	\$74.60		0.47%
6/20/2001	\$74.66		0.08%
6/21/2001	\$74.47		-0.25%
6/22/2001	\$67.80		-9.38%
6/25/2001	\$67.50		-0.44%
6/26/2001	\$66.22		-1.91%
6/27/2001	\$65.64		-0.88%
6/28/2001	\$65.00		-0.98%
6/29/2001	\$63.91		-1.69%
7/2/2001	\$64.35		0.69%
7/3/2001	\$64.70		0.54%
7/5/2001	\$64.14		-0.87%
7/6/2001	\$63.44		-1.10%
7/9/2001	\$64.60		1.81%
7/10/2001	\$63.72		-1.37%
7/11/2001	\$62.36		-2.16%
7/12/2001	\$61.00		-2.21%
7/13/2001	\$61.50		0.82%

**Exhibit-5**

**Merck & Co., Inc.**

**Common Stock Prices, Dividends and Returns**

<b>Date</b>	<b>MRK Closing Stock Price</b>	<b>MRK Dividend</b>	<b>MRK Logarithmic Return</b>
7/16/2001	\$62.98		2.38%
7/17/2001	\$64.48		2.35%
7/18/2001	\$67.55		4.65%
7/19/2001	\$67.30		-0.37%
7/20/2001	\$66.43		-1.30%
7/23/2001	\$65.70		-1.10%
7/24/2001	\$64.93		-1.18%
7/25/2001	\$64.99		0.09%
7/26/2001	\$64.76		-0.35%
7/27/2001	\$65.14		0.59%
7/30/2001	\$66.25		1.69%
7/31/2001	\$67.98		2.58%
8/1/2001	\$67.99		0.01%
8/2/2001	\$67.79		-0.29%
8/3/2001	\$68.11		0.47%
8/6/2001	\$67.42		-1.02%
8/7/2001	\$68.48		1.56%
8/8/2001	\$67.85		-0.92%
8/9/2001	\$67.82		-0.04%
8/10/2001	\$69.03		1.77%
8/13/2001	\$69.65		0.89%
8/14/2001	\$70.00		0.50%
8/15/2001	\$68.90		-1.58%
8/16/2001	\$69.99		1.57%
8/17/2001	\$69.15		-1.21%
8/20/2001	\$70.58		2.05%
8/21/2001	\$70.75		0.24%
8/22/2001	\$71.22		0.66%
8/23/2001	\$68.51		-3.88%
8/24/2001	\$69.02		0.74%
8/27/2001	\$68.70		-0.46%
8/28/2001	\$68.01		-1.01%
8/29/2001	\$67.14		-1.29%
8/30/2001	\$65.99	\$0.35	-1.20%
8/31/2001	\$65.10		-1.36%
9/4/2001	\$65.30		0.31%
9/5/2001	\$67.70		3.61%

**Exhibit-5**

**Merck & Co., Inc.**

**Common Stock Prices, Dividends and Returns**

<b>Date</b>	<b>MRK Closing Stock Price</b>	<b>MRK Dividend</b>	<b>MRK Logarithmic Return</b>
9/6/2001	\$65.75		-2.92%
9/7/2001	\$64.30		-2.23%
9/10/2001	\$66.10		2.76%
9/17/2001	\$67.15		1.58%
9/18/2001	\$68.31		1.71%
9/19/2001	\$67.86		-0.66%
9/20/2001	\$66.85		-1.50%
9/21/2001	\$65.70		-1.74%
9/24/2001	\$63.99		-2.64%
9/25/2001	\$62.45		-2.44%
9/26/2001	\$63.35		1.43%
9/27/2001	\$66.21		4.42%
9/28/2001	\$66.60		0.59%
10/1/2001	\$68.32		2.55%
10/2/2001	\$68.44		0.18%
10/3/2001	\$67.66		-1.15%
10/4/2001	\$67.10		-0.83%
10/5/2001	\$68.26		1.71%
10/8/2001	\$68.60		0.50%
10/9/2001	\$67.93		-0.98%
10/10/2001	\$68.49		0.82%
10/11/2001	\$68.18		-0.45%
10/12/2001	\$69.16		1.43%
10/15/2001	\$69.95		1.14%
10/16/2001	\$69.31		-0.92%
10/17/2001	\$69.05		-0.38%
10/18/2001	\$66.30		-4.06%

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**Source:**

CRSP

## Exhibit-6

### Merck Stock Regression Results

Estimation Period: 19 October 2000 to 18 October 2001

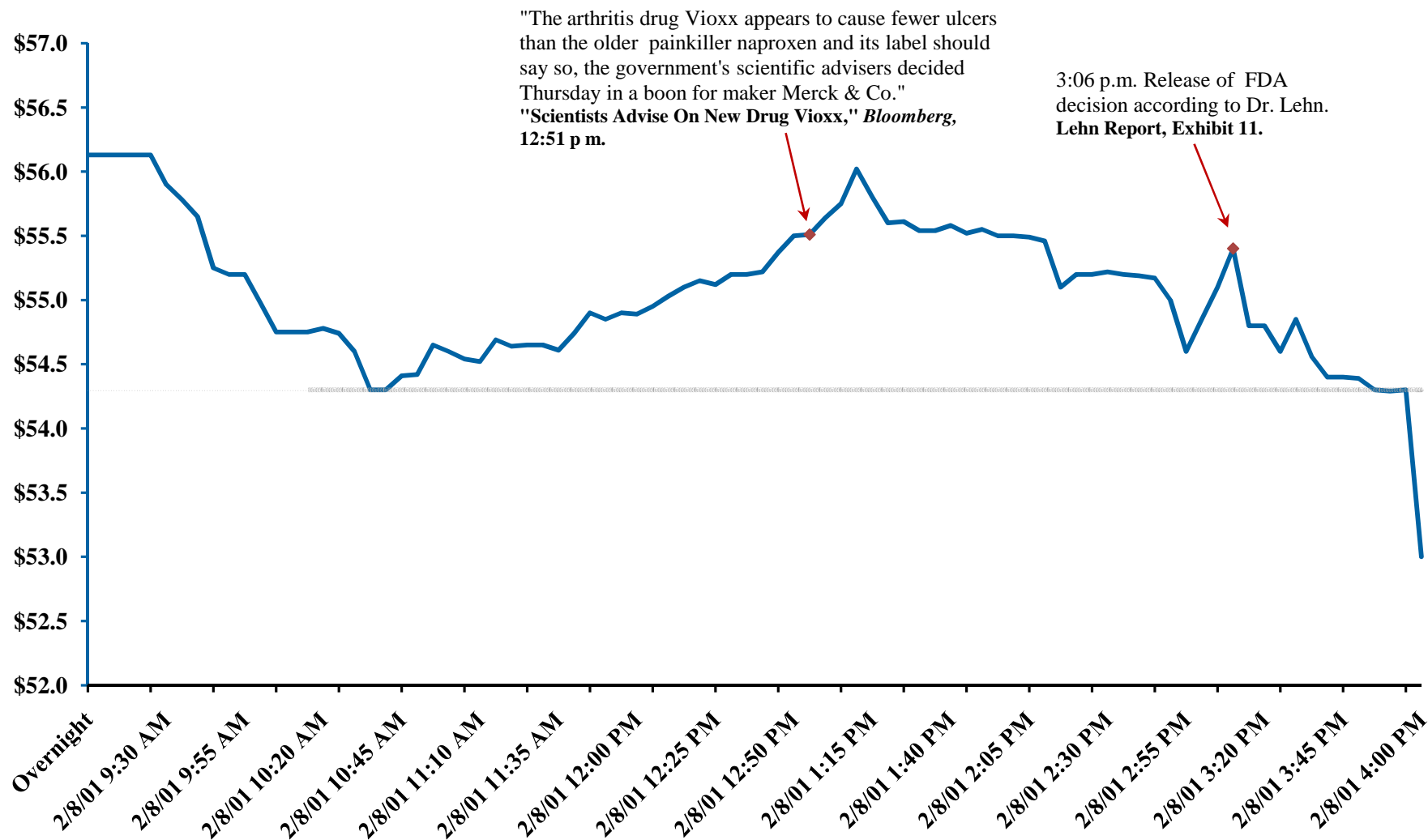
Regression Statistics	
Multiple R	0.663
R Square	0.440
Adjusted R Square	0.424
Standard Error	1.46%
Observations	248
F-Statistic	26.93
F-Statistic Significance Level	~0%

	Coefficients	Standard Error	<i>t</i> -statistic
Intercept	-0.05%	0.09%	-0.549
Market Index	-0.096	0.063	-1.521
Peer Index	0.920	0.068	13.434
6 February 2001	0.48%	1.46%	0.330
7 February 2001	-4.14%	1.47%	-2.825
8 February 2001	0.95%	1.46%	0.650
9 February 2001	-0.46%	1.47%	-0.315
12 February 2001	-0.48%	1.47%	-0.328

**Exhibit-7**  
**Merck & Co., Inc.**  
**Common Stock Event Study Results**

<b>Date</b>	<b>MRK Closing Stock Price</b>	<b>MRK Closing Stock Price on Prior Trading Day</b>	<b>MRK Logarithmic Return</b>	<b>Market Index Logarithmic Return</b>	<b>Pharma Index Logarithmic Return</b>	<b>MRK Explained Return</b>	<b>MRK Residual Return</b>	<b>t-statistic</b>	<b>p-value</b>	<b>Statistically Significant</b>
7 February 2001	\$81.85	\$84.36	-3.02%	-0.88%	1.19%	1.13%	-4.15%	-2.83	0.0050	Yes
8 February 2001	\$82.97	\$81.85	1.36%	-0.65%	0.43%	0.41%	0.95%	0.65	0.5166	No
9 February 2001	\$82.72	\$82.97	-0.30%	-1.44%	0.08%	0.16%	-0.46%	-0.32	0.7518	No
12 February 2001	\$82.98	\$82.72	0.31%	1.03%	1.03%	0.79%	-0.48%	-0.33	0.7425	No
7-9 February 2001			-1.96%	-2.97%	1.70%	1.70%	-3.66%	-1.44	0.1499	No
8-12 February 2001			1.37%	-1.06%	1.54%	1.37%	0.01%	0.00	0.9982	No

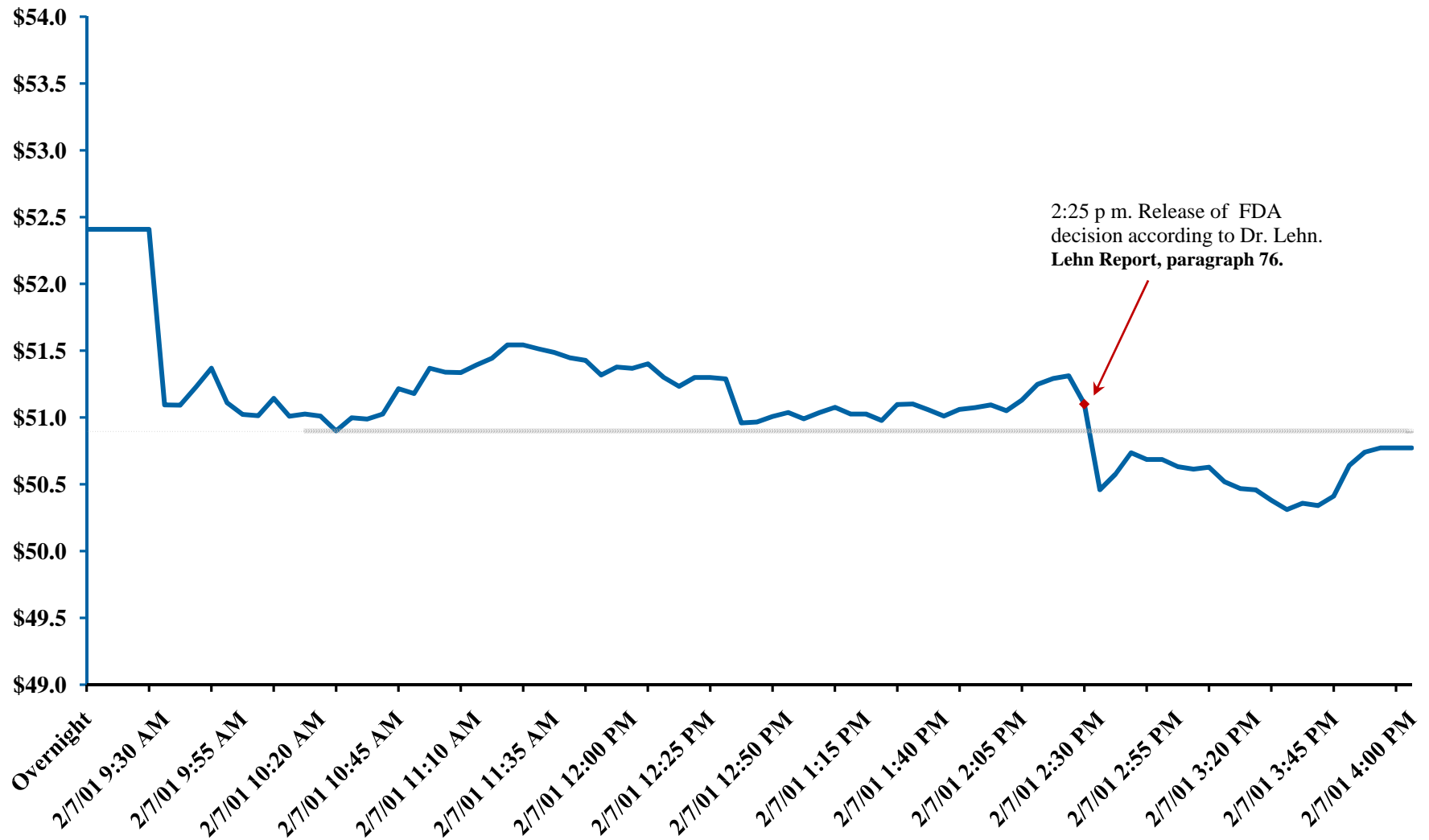
**Exhibit-8**  
**Pharmacia Corp.**  
**Intraday Stock Price: 8 February 2001**



Source: TAQ.

Note: For comparison purposes the stock price data represents the last transaction price of each five minute increment.

**Exhibit-9**  
**Pharmacia Pharmaceuticals**  
**Intraday Stock Price: 7 Febraury 2001**



Source: TAQ.

Note: For comparison purposes the stock price data represents the last transaction price of each five minute increment.

# EXHIBIT 8



<p style="text-align: center;">1</p> <p style="text-align: center;">UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY</p> <p>ALASKA ELECTRICAL PENSION ) FUND, et al., On Behalf of ) Themselves and All Others ) No. 03-1519 Similarly Situated, ) (AET) Plaintiffs, ) vs. ) PHARMACIA CORPORATION, et al., ) Defendants. )</p> <p>The deposition of STEVEN GEIS, called for examination, taken before NICOLE SCOLA, CSR No. 084-004524, a Notary Public within and for the County of DuPage, State of Illinois, and a Certified Shorthand Reporter of said state, at Suite 900, One South Dearborn Street, Chicago, Illinois, on December 10, 2010, at 9:06 a.m.</p>	<p style="text-align: center;">3</p> <p>1 ALSO PRESENT:</p> <p>2</p> <p>3 MR. KEVIN DAILEY, Legal Videographer,</p> <p>4 Esquire Deposition Solutions.</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23 REPORTED BY: NICOLE M. SCOLA, CSR, RPR,</p> <p>24 C.S.R. Certificate No. 84-4524.</p>
<p style="text-align: center;">2</p> <p>1 PRESENT:</p> <p>2</p> <p>3 ROBBINS GELLER RUDMAN &amp; DOWD, LLP,</p> <p>4 (665 West Broadway, Suite 1900,</p> <p>5 San Diego, California 92101,</p> <p>6 619-231-1058), by:</p> <p>7 MR. SCOTT H. SAHAM,</p> <p>8 MR. LUCAS F. OLTS,</p> <p>9 -and-</p> <p>10 SCOTT &amp; SCOTT LLP,</p> <p>11 (707 Broadway, Suite 1000,</p> <p>12 San Diego, California 92101,</p> <p>13 619-233-4565), by:</p> <p>14 MR. MATTHEW MONTGOMERY,</p> <p>15 appeared on behalf of the Plaintiffs;</p> <p>16</p> <p>17 CADWALADER, WICKERSHAM &amp; TAFT LLP,</p> <p>18 (One World Financial Center,</p> <p>19 New York, New York 10281,</p> <p>20 212-504-6474), by:</p> <p>21 MR. JONATHAN M. HOFF,</p> <p>22 MR. JOSHUA R. WEISS,</p> <p>23 appeared on behalf of the Defendants.</p> <p>24</p>	<p style="text-align: center;">4</p> <p>1 THE VIDEOGRAPHER: Good morning. We're going</p> <p>2 on the video record at 9:06 a.m.</p> <p>3 My name is Kevin Dailey, and I'm a legal</p> <p>4 videographer in association with Esquire Deposition</p> <p>5 Solutions. Our address is 311 West Monroe, Chicago,</p> <p>6 Illinois.</p> <p>7 The court reporter is Nicole Scola, also</p> <p>8 of Esquire Deposition Solutions.</p> <p>9 Here begins the videotaped deposition of</p> <p>10 Steven Geis, taking place at One South Dearborn,</p> <p>11 Chicago, Illinois.</p> <p>12 Today's date is December 10, 2010.</p> <p>13 This deposition is being taken in the</p> <p>14 matter of Alaska Electrical Pension Fund, et al. vs.</p> <p>15 Pharmacia Corporation, et al., being heard before</p> <p>16 the United States District Court, the District of</p> <p>17 New Jersey.</p> <p>18 Will counsel please state their names for</p> <p>19 the record.</p> <p>20 MR. SAHAM: Scott Saham for the plaintiffs.</p> <p>21 MR. MONTGOMERY: Matt Montgomery for the</p> <p>22 plaintiffs.</p> <p>23 MR. OLTS: Lucas Olts for the plaintiffs.</p> <p>24 MR. HOFF: Jonathan Hoff for the defendants.</p>



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<p>5</p> <p>1 MR. WEISS: Joshua Weiss for the defendants.</p> <p>2 THE VIDEOGRAPHER: Will the reporter please</p> <p>3 swear in the witness.</p> <p>4 (WHEREUPON, the witness was duly</p> <p>5 sworn.)</p> <p>6 STEVEN GEIS,</p> <p>7 called as a witness herein, having been first duly</p> <p>8 sworn, was examined and testified as follows:</p> <p>9 EXAMINATION</p> <p>10 BY MR. SAHAM:</p> <p>11 Q. Good morning, Dr. Geis.</p> <p>12 A. Good morning.</p> <p>13 Q. Could you please state and spell your</p> <p>14 name for the record?</p> <p>15 A. It's Steven Geis, G-e-i-s.</p> <p>16 Q. And what is your current address?</p> <p>17 A. 1945 North Seminary, Chicago,</p> <p>18 Illinois 60614.</p> <p>19 Q. And is there any reason today why you</p> <p>20 cannot provide truthful and complete testimony,</p> <p>21 medical or otherwise?</p> <p>22 A. No, there isn't.</p> <p>23 Q. Now, bringing you back to the 1998</p> <p>24 through 2001 time frame, where were you employed?</p>	<p>7</p> <p>1 Q. Okay. Tell me the two job titles.</p> <p>2 A. I think there were three. But in 1998, I</p> <p>3 was -- and I might have this wrong -- an</p> <p>4 executive -- an executive director for arthritis,</p> <p>5 inflammation and pain.</p> <p>6 In the summer of 1999, I was promoted to</p> <p>7 vice president for the therapeutic area of</p> <p>8 arthritis, inflammation and pain.</p> <p>9 After the merger with Pharmacia, I became</p> <p>10 the global vice president for arthritis,</p> <p>11 inflammation and pain, cardiovascular disease and</p> <p>12 oncology.</p> <p>13 Q. And -- and during that time period, did</p> <p>14 you work on the CLASS trial or CLASS study?</p> <p>15 A. Yes, I did.</p> <p>16 Q. And what were your responsibilities with</p> <p>17 respect to CLASS?</p> <p>18 A. I provided oversight for the -- the team</p> <p>19 that conducted the clinical trial.</p> <p>20 Q. Okay. And prior to that, did you work on</p> <p>21 the NDA for Celebrex or Celecoxib?</p> <p>22 A. Yes, I did.</p> <p>23 Q. And what was your responsibility with</p> <p>24 respect to the NDA?</p>
<p>6</p> <p>1 A. I was employed -- from 9 -- 1998, I was</p> <p>2 employed by G.D. Searle &amp; Company, and then after</p> <p>3 the merger with Pharmacia into the 2001, I think you</p> <p>4 said was the later date, I was an employee for</p> <p>5 Pharmacia.</p> <p>6 Q. Okay. And during that time frame, did</p> <p>7 you work with respect to a drug called Celebrex?</p> <p>8 A. Yes, I did.</p> <p>9 Q. Okay. And what was your job title at</p> <p>10 G.D. Searle?</p> <p>11 A. During that period?</p> <p>12 Q. Yeah, during -- well, I'll -- I'll</p> <p>13 represent to you, and we can show you a document --</p> <p>14 A. Sure.</p> <p>15 Q. -- later, that the merger with Pharmacia</p> <p>16 closed on March 31st of the year 2000.</p> <p>17 A. Okay.</p> <p>18 Q. So in the 1998 through March 31st, 2000,</p> <p>19 prior to the merger when you worked at</p> <p>20 G.D. Searle --</p> <p>21 A. Okay.</p> <p>22 Q. -- what was your job title?</p> <p>23 A. My job title changed over that period</p> <p>24 that you just described.</p>	<p>8</p> <p>1 A. To provide oversight for the team that</p> <p>2 were conducting the clinical trials and putting the</p> <p>3 NDA together.</p> <p>4 Q. And were you the first-line manager with</p> <p>5 respect to those Celebrex NDA and the CLASS trial?</p> <p>6 MR. HOFF: Objection to form.</p> <p>7 BY THE WITNESS:</p> <p>8 A. Tell me what you mean by "first-line</p> <p>9 manager."</p> <p>10 BY MR. SAHAM:</p> <p>11 Q. Well, I --</p> <p>12 A. That's not terminology used.</p> <p>13 Q. Sure. I understand that there are</p> <p>14 individuals at the companies --</p> <p>15 A. Sure.</p> <p>16 Q. -- ranked above you in the chain of</p> <p>17 command, but were you the main executive responsible</p> <p>18 for those projects?</p> <p>19 A. The -- the clinical trials were conducted</p> <p>20 by my team. The NDA was put together predominantly</p> <p>21 by my team, and I provided oversight for that team.</p> <p>22 That's what I can tell you.</p> <p>23 Q. That's fine. That's -- that's all I was</p> <p>24 trying to understand.</p>



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<p>9</p> <p>1 And I'd like to show you what I've marked</p> <p>2 here as Plaintiffs' Exhibit 248.</p> <p>3 Could you take a look at that document?</p> <p>4 (WHEREUPON, a certain document was</p> <p>5 marked Plaintiffs' Deposition</p> <p>6 Exhibit No. 248, for identification,</p> <p>7 as of 12/10/2010.)</p> <p>8 BY MR. SAHAM:</p> <p>9 Q. Tell me if you recognize it.</p> <p>10 MR. SAHAM: For the record, 248 bears</p> <p>11 Bates numbers DEFS 00113653 through 69.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Okay.</p> <p>14 BY MR. SAHAM:</p> <p>15 Q. Do you recognize this document?</p> <p>16 A. Yes.</p> <p>17 Q. And what is it?</p> <p>18 A. This is a -- what -- I haven't read every</p> <p>19 word of it, but it appears to be an old version of</p> <p>20 what I would call my CV.</p> <p>21 Q. Okay. And that's your curriculum vitae?</p> <p>22 A. Yes.</p> <p>23 Q. And does it appear to be -- well, strike</p> <p>24 that question.</p> <p>10</p> <p>1 It -- what is the purpose of your CV?</p> <p>2 A. Well, in our profession, in the medical</p> <p>3 and scientific communities, we put together, I think</p> <p>4 what in other circles is called a -- they use a</p> <p>5 different term, but what this is, is, what is your</p> <p>6 work experience, historically, what is your</p> <p>7 educational background and what are the publications</p> <p>8 that you have -- your -- awards you've received,</p> <p>9 civic contributions and the publications that you</p> <p>10 have had published.</p> <p>11 Q. And at the beginning of the -- of your</p> <p>12 CV, it -- there's a section entitled Objective?</p> <p>13 A. Yes.</p> <p>14 Q. And right at the beginning there, it</p> <p>15 states that you were at least partly responsible for</p> <p>16 developing the blockbuster drug Celebrex; is that</p> <p>17 correct?</p> <p>18 A. Let me take a look at this.</p> <p>19 Yes, that's what that says.</p> <p>20 Q. And it also emphasizes that you</p> <p>21 participated in submitting the Celecoxib NDA? And</p> <p>22 I'm moving down to your first job description under</p> <p>23 Vice President: Arthritis Clinical Development --</p> <p>24 A. Right.</p>	<p>11</p> <p>1 Q. -- August 1998 to the present.</p> <p>2 A. Could you repeat the question?</p> <p>3 Q. My question is, this just emphasizes that</p> <p>4 you were, in part, responsible for submitting the</p> <p>5 Celecoxib NDA; is that correct?</p> <p>6 A. Yes, that was part of my</p> <p>7 responsibilities.</p> <p>8 Q. Okay. And during this time period that</p> <p>9 I'm focused on -- and I -- I guess I'd ask the</p> <p>10 question in two parts.</p> <p>11 Initially, between August of '98 and the</p> <p>12 merger in March of -- of 2001, did you report to</p> <p>13 Dr. Friedman? Is that correct?</p> <p>14 A. So March of 1998?</p> <p>15 Q. No, I'm sorry, just -- well -- well,</p> <p>16 let's make the question simpler.</p> <p>17 The -- the -- during 1999 and up until</p> <p>18 March of 2000 when the merger occurred, the end of</p> <p>19 March of 2000, did you report to Dr. Michael</p> <p>20 Friedman?</p> <p>21 A. On -- yes, in principle, but there may</p> <p>22 have been a short period of time before that where</p> <p>23 Michael Friedman's predecessor was John Alexander,</p> <p>24 and I reported to him, and then Friedman came in.</p> <p>12</p> <p>1 Q. Okay. And then Dr. Friedman reported to</p> <p>2 Dr. Needleman; is that correct?</p> <p>3 A. I believe so, that was the reporting</p> <p>4 structure.</p> <p>5 Q. Okay. And then once the merger occurred</p> <p>6 in March of 2000, the end of March of 2000, who did</p> <p>7 you report to then?</p> <p>8 A. Frankly, it got a little bit uncertain as</p> <p>9 to when the new structure went in place, and I</p> <p>10 reported to a new boss versus when I was still</p> <p>11 reporting to Michael Friedman.</p> <p>12 Q. Okay.</p> <p>13 A. But ultimately, as things evolved, I</p> <p>14 reported to Mike Tansey at Pharmacia.</p> <p>15 Q. And it --</p> <p>16 A. And it was probably toward the end of</p> <p>17 2000 -- mid to end.</p> <p>18 Q. Okay. And then who -- who did Mr. Tansey</p> <p>19 report to?</p> <p>20 A. Dr. Tansey, I believe, reported directly</p> <p>21 to Dr. Goran Ando.</p> <p>22 Q. Okay. And where was Dr. Needleman in</p> <p>23 that?</p> <p>24 A. I can't say for sure because this -- this</p>
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<p>13</p> <p>1 was -- appeared to me, with the merger, an evolving</p> <p>2 situation as to what the roles and responsibilities</p> <p>3 would be to -- for the people who were a couple</p> <p>4 levels above me. So Dr. Needleman was still there.</p> <p>5 My understanding was, he shared responsibility for</p> <p>6 R&amp;D with Dr. Ando.</p> <p>7 Q. So Dr. Ando and Dr. Needleman were chief</p> <p>8 of R&amp;D at Pharmacia?</p> <p>9 A. I can't say explicitly in terms of how I</p> <p>10 saw it from where I was. They were both providing</p> <p>11 guidance to R&amp;D, but I can't tell you I ever saw an</p> <p>12 organizational structure that said, here's two guys,</p> <p>13 and this is what they're doing.</p> <p>14 Q. Okay. But they were both above you at</p> <p>15 Pharmacia; is that correct?</p> <p>16 A. Oh, yes.</p> <p>17 Q. Okay. And -- and they both reported to</p> <p>18 the CEO of the company, Mr. Hassan?</p> <p>19 A. Directly reported? See, I don't know.</p> <p>20 Q. Okay. Well, if you don't know, you don't</p> <p>21 know.</p> <p>22 A. I don't know.</p> <p>23 Q. Okay. And do you recall who -- in that</p> <p>24 2000 time frame, who -- who was your team of direct</p>	<p>15</p> <p>1 CLASS trial, is it correct that you signed off on</p> <p>2 the protocols?</p> <p>3 A. You know, I'd have to look at those</p> <p>4 protocols, because the -- the procedure changed over</p> <p>5 time, whether or not the director of the team was</p> <p>6 supposed to sign off.</p> <p>7 Because for a while, we were supposed to</p> <p>8 sign off, and then they changed the process and they</p> <p>9 said the directors don't sign off. The medical guys</p> <p>10 actually running the studies sign off. So I'd have</p> <p>11 to look at the actual sign-off page to see.</p> <p>12 Q. And I'll show you that in -- momentarily.</p> <p>13 But it -- it -- it's correct to say that</p> <p>14 you participated in the design of the CLASS trial?</p> <p>15 A. Yes, that's correct.</p> <p>16 Q. And it's also correct to say that you</p> <p>17 participated in the analysis of the data once it was</p> <p>18 unblinded?</p> <p>19 A. Yes.</p> <p>20 Q. And you started that process immediately</p> <p>21 after unblinding?</p> <p>22 A. Immediately -- well, shortly after it was</p> <p>23 unblinded and I was given the data, we started it.</p> <p>24 Q. And is it also accurate that you were the</p>
<p>14</p> <p>1 reports, to the extent you can recall them?</p> <p>2 A. Wow. So there were many people on the</p> <p>3 team. And, again, the -- the reporting</p> <p>4 relationships were moving because the organization</p> <p>5 was changing and then -- and then we threw on top of</p> <p>6 that the merger with Pharmacia. So I don't know if</p> <p>7 I can say explicitly everybody who reported directly</p> <p>8 to me.</p> <p>9 Q. Just to make it easier --</p> <p>10 A. I can tell you --</p> <p>11 Q. -- who --</p> <p>12 A. -- some of them.</p> <p>13 Q. -- who do you recall that worked on the</p> <p>14 Celecoxib team below you in that --</p> <p>15 A. Okay.</p> <p>16 Q. -- point in time?</p> <p>17 A. Okay. So Dr. Ken Verburg, Dr. Jim</p> <p>18 Lefkowitz, Dr. Jeff Kent, Aimee Burr. And that</p> <p>19 would have been direct reporting to me.</p> <p>20 Then there were -- were other people --</p> <p>21 excuse me -- from other departments, such as</p> <p>22 statistics and data management, who worked on it but</p> <p>23 did not directly report to me.</p> <p>24 Q. Okay. And -- and with respect to the</p>	<p>16</p> <p>1 senior author on the JAMA paper that was published</p> <p>2 in September of 2000 regarding the CLASS trial?</p> <p>3 MR. HOFF: Objection to form.</p> <p>4 BY THE WITNESS:</p> <p>5 A. I don't know what you mean by "the senior</p> <p>6 author."</p> <p>7 BY MR. SAHAM:</p> <p>8 Q. Well, there were 13 authors and you were</p> <p>9 the last one listed.</p> <p>10 Is that commonly referred to as the</p> <p>11 senior author?</p> <p>12 A. No.</p> <p>13 Q. Okay. You haven't heard the last author</p> <p>14 being listed as the senior author?</p> <p>15 A. No.</p> <p>16 Q. Is there any import of being the last</p> <p>17 person listed or the first person listed on a</p> <p>18 medical article?</p> <p>19 A. I think some people give import to it in</p> <p>20 some circles. I don't necessarily do it.</p> <p>21 Q. Okay. And that import would be, the</p> <p>22 first and last are the most prestigious places to</p> <p>23 be?</p> <p>24 A. Not to me, but some people would say</p>



<p>17</p> <p>1 that.</p> <p>2 Q. One last question about your resume,</p> <p>3 which is -- or your CV, which is Exhibit 248.</p> <p>4 On the third page of the document under</p> <p>5 Awards, you're awarded the Edgar M. Queeny award.</p> <p>6 Do you see that?</p> <p>7 A. Yes.</p> <p>8 Q. And what's the Edgar M. Queeny award?</p> <p>9 A. In the Monsanto organization, this was an</p> <p>10 award that was given.</p> <p>11 Q. Okay. And what -- what was the point of</p> <p>12 the award?</p> <p>13 A. My understanding is that it was given to</p> <p>14 people who played a key role in taking a product</p> <p>15 from more of the concept or the basic science stage</p> <p>16 through commercialization.</p> <p>17 Q. And you were awarded that for playing a</p> <p>18 key role with respect to Celebrex; is that correct?</p> <p>19 A. I was awarded it with a number of other</p> <p>20 people, yes.</p> <p>21 Q. But with respect to your work on</p> <p>22 Celebrex?</p> <p>23 A. Yes.</p> <p>24 Q. Okay.</p>	<p>19</p> <p>1 Exhibit No. 77.</p> <p>2 Could you please take a look at</p> <p>3 Plaintiffs' Exhibit 77.</p> <p>4 MR. SAHAM: Do you guys want two, or should I</p> <p>5 give them one?</p> <p>6 Thank you, Josh.</p> <p>7 BY MR. SAHAM:</p> <p>8 Q. And just quickly, you don't have to --</p> <p>9 you know, it's a lengthy document, but could you</p> <p>10 just tell me what Exhibit 77 is, if you recognize</p> <p>11 it?</p> <p>12 A. The title of it is a revised clinical</p> <p>13 protocol for the multi-center, double-blind,</p> <p>14 parallel group study comparing the incidence of</p> <p>15 clinically significant upper gastrointestinal</p> <p>16 reverse events associated with SC-58635</p> <p>17 400 milligrams BID to that of Diclofenac</p> <p>18 75 milligrams BID in patients with osteoarthritis or</p> <p>19 rheumatoid arthritis, IDN # 48395, original protocol</p> <p>20 number N48-98-02-102(sic) (Revision 1).</p> <p>21 Q. And do you recognize that -- this as</p> <p>22 being one of the protocols or amended protocols with</p> <p>23 respect to the CLASS trial and the comparison to</p> <p>24 Diclofenac?</p>
<p>18</p> <p>1 A. That's correct.</p> <p>2 Q. And I'd like to show you what's</p> <p>3 previously been marked in this case as -- or before</p> <p>4 I do that -- actually, I'll strike that question.</p> <p>5 Additionally, when we were talking about</p> <p>6 your -- your role with CLASS just a minute ago, you</p> <p>7 also -- after the -- the data was -- was analyzed</p> <p>8 and presented to the public, you -- you participated</p> <p>9 on behalf of Pharmacia in talking about the data in</p> <p>10 certain circles; is that correct?</p> <p>11 It's a bad question. I can ask it</p> <p>12 differently.</p> <p>13 You -- you communicated publicly about</p> <p>14 the CLASS data on behalf of Pharmacia, correct?</p> <p>15 A. At -- at some point in time, I did.</p> <p>16 Q. And -- and I'm talking about in 2000,</p> <p>17 after the data was unblinded and you analyzed it,</p> <p>18 you communicated on behalf of Pharmacia about the</p> <p>19 data to the public?</p> <p>20 A. I think you -- I commun- - I communicated</p> <p>21 to the public, I guess, as a representative of</p> <p>22 Pharmacia would be accurate.</p> <p>23 Q. Okay. I want to show you what's</p> <p>24 previously been marked in this case as Plaintiffs'</p>	<p>20</p> <p>1 A. Could you repeat the question?</p> <p>2 Q. My question is, do you recognize this as</p> <p>3 being one of the revised protocols with respect to</p> <p>4 the CLASS trial and the comparison between Celecoxib</p> <p>5 and Diclofenac?</p> <p>6 A. Yes, this is part of the protocol.</p> <p>7 Q. Okay. And if you turn to the second page</p> <p>8 of the document, is that your signature?</p> <p>9 A. Yes, it is.</p> <p>10 Q. And what was the purpose of your</p> <p>11 signature here as vice president of clinical</p> <p>12 research?</p> <p>13 A. To acknowledge that this was the final</p> <p>14 document to be put to use.</p> <p>15 Q. And it's -- you dated the document</p> <p>16 October 27, 1998?</p> <p>17 A. Yes, I did.</p> <p>18 Q. Okay. And I'd like to refer you to --</p> <p>19 well, let me just ask you generally, what's the</p> <p>20 purpose of the revised clinical protocol?</p> <p>21 A. So first, maybe to tell you what a</p> <p>22 protocol is, so the protocol is, the instructions as</p> <p>23 to -- to -- it describes the intent of the study,</p> <p>24 gives instructions as to how to conduct the study</p>



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<p style="text-align: center;">21</p> <p>1 and how we're going to analyze the study.</p> <p>2 There are circumstances where after the</p> <p>3 original protocol is signed, that a change is</p> <p>4 desired to be made. So a revision is made for the</p> <p>5 protocol, and in our -- in our practice, although it</p> <p>6 isn't 100 percent of the case, the protocol is</p> <p>7 rewritten to incorporate the revisions into the</p> <p>8 document so there is one document.</p> <p>9 Q. Okay. And I -- I'd like to turn your</p> <p>10 attention, if I could -- there's numbers in the top</p> <p>11 right-hand corner -- to page 10 of 36. And under</p> <p>12 Objectives, there's listed 2.1 Primary Objective.</p> <p>13 Do you see that?</p> <p>14 A. Yes, I do.</p> <p>15 Q. And that lays out the primary objective</p> <p>16 of the study; is that correct?</p> <p>17 A. It lays out the primary objective of this</p> <p>18 particular protocol, which is part of two that</p> <p>19 satisfies a larger objective.</p> <p>20 Q. Right. And that's because there's --</p> <p>21 there's -- and just correct me if I get this</p> <p>22 wrong -- there's the CLASS trial and there's one arm</p> <p>23 comparing Celecoxib to Ibuprofen, and then there's a</p> <p>24 separate arm comparing it to Diclofenac, and this is</p>	<p style="text-align: center;">23</p> <p>1 Q. -- want to lay out to you that there's --</p> <p>2 there's two separate protocols that are very</p> <p>3 similar, but one deals with the comparison or the</p> <p>4 conduct of the study with respect to Celebrex and</p> <p>5 Diclofenac, and then there's a similar one that</p> <p>6 deals with Ibuprofen. That's all I'm trying to</p> <p>7 understand.</p> <p>8 A. Yeah, I think that's a fair description.</p> <p>9 Q. Okay. And this one that we're looking</p> <p>10 at, Exhibit 77, is the Diclofenac part of that?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. And looking at Primary Objective</p> <p>13 2.1, that lays out that the primary objective of the</p> <p>14 study is to compare incidence of clinically</p> <p>15 significant upper gastrointestinal adverse events.</p> <p>16 And then it goes on to say, A composite</p> <p>17 safety endpoint comprised of perforation, bleeding</p> <p>18 or gastric outlet obstruction associated with</p> <p>19 SC-58635 400 milligram BID to that associated with</p> <p>20 Diclofenac 75 MG BID in patients with OA or RA.</p> <p>21 Is -- is that an accurate reading of the</p> <p>22 primary objective as spelled out in this protocol?</p> <p>23 A. The primary objective of this particular</p> <p>24 protocol, yes --</p>
<p style="text-align: center;">22</p> <p>1 the Diclofenac arm protocol?</p> <p>2 A. I don't put it in those terms. When you</p> <p>3 talk about arms of the study, you talk about one arm</p> <p>4 is Celecoxib and people who are treated with</p> <p>5 Celecoxib. The other arm and the overriding</p> <p>6 objective of the CLASS trial was the NSAIDs combined</p> <p>7 in all patients receiving NSAIDs.</p> <p>8 So there's two arms to the study. Within</p> <p>9 the NSAIDs group, there was two different NSAIDs.</p> <p>10 Q. And -- and this just spells out how the</p> <p>11 comparison is going to be conducted between</p> <p>12 Celecoxib and Diclofenac -- this protocol?</p> <p>13 A. This protocol describes how to conduct</p> <p>14 the clinical trial in patients who are going to</p> <p>15 receive Diclofenac in this trial versus Celebrex.</p> <p>16 It does, then, give some -- I believe there's a</p> <p>17 statistical section in here --</p> <p>18 Q. We'll get to that in a second.</p> <p>19 A. -- which talks about -- because I think</p> <p>20 your question had to do with analyze, how it'll be</p> <p>21 analyzed.</p> <p>22 Q. No, I'm not -- and I'm not trying to be</p> <p>23 tricky. I -- I just --</p> <p>24 A. No.</p>	<p style="text-align: center;">24</p> <p>1 Q. Okay.</p> <p>2 A. -- that is accurate.</p> <p>3 Q. And -- and just to make things easier for</p> <p>4 the rest of the day, where it's talking about these</p> <p>5 clinically significant upper gastrointestinal</p> <p>6 adverse events, you, periodically, and you and your</p> <p>7 team and the folks at Pharmacia, you refer to those</p> <p>8 as -- I call them CSUGIEs, C-S-U-G-I-E; is -- is</p> <p>9 that accurate? That's one of the ways you refer to</p> <p>10 these?</p> <p>11 A. No.</p> <p>12 Q. What -- what would you call them? I</p> <p>13 mean --</p> <p>14 A. The --</p> <p>15 Q. -- the -- what acronym?</p> <p>16 A. That was the team. The people who were,</p> <p>17 like, working on them day-to-day called them</p> <p>18 CSUGIEs.</p> <p>19 Q. CSUGIE, but that's C-S-U-G-I-E?</p> <p>20 A. Yeah, clinically significant upper GI</p> <p>21 events.</p> <p>22 Q. And when we see that acronym in a</p> <p>23 document, it's referring to this?</p> <p>24 A. Yes.</p>



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<p style="text-align: center;">25</p> <p>1 Q. And you also could call that a 2 complicated ulcer; is that correct? 3 A. I tend to call it complicated ulcer. 4 Q. Okay. Or an ulcer -- 5 A. That's the language I -- I'm used to 6 using. 7 Q. Or some people call it an ulcer 8 complication, as well? 9 A. Yeah. 10 Q. So when we're looking at the documents, 11 we can -- 12 A. Yes. 13 Q. -- agree that that's all referring to the 14 same thing, unless you say -- 15 A. Yeah. 16 Q. -- different? 17 A. Yeah. There may be times when we have to 18 dissect it apart a bit, but -- 19 Q. Okay. 20 A. -- yes, in principle, I would say yes. 21 Q. Okay. And sometimes people call them a 22 POB or a perforation, obstruction or bleed? 23 A. Right. 24 Q. Okay. Great.</p>	<p style="text-align: center;">27</p> <p>1 a half pages long, what's the purpose of this 2 section in the protocol, generally? 3 A. Let me go back. 4 So this section, 5.5, is part of a bigger 5 section called Statistics. 6 Q. I can ask a more specific question -- 7 A. Sure. 8 Q. -- if it would be easier. 9 A. But it is -- it is a -- a -- a shortened 10 version of the overriding statistical analysis plan 11 which will be used for the CLASS trial. 12 Q. And -- and this lays out that there's -- 13 there's two coprimary endpoints to be analyzed; is 14 that correct? 15 A. I need to -- 16 Q. Specifically -- 17 A. -- look at it. 18 Q. -- if you look -- I can -- I can help you 19 here. If you go to page 30, the second paragraph, 20 it states, Two endpoints will be analyzed. One is 21 based on the traditional definition and the other 22 alternative one is proposed by the FDA. These two 23 endpoints will be considered as coprimary; is that 24 correct?</p>
<p style="text-align: center;">26</p> <p>1 A. Right. 2 Q. And then I'd like to turn your attention 3 now to page 20 of 36, so 10 pages further on. And 4 there's a Section 4.3 Treatment Period. 5 Do you see that? 6 A. Yes, I do. 7 Q. And it says the treatment period is 8 defined as the four -- 52-week interval during which 9 study medication is taken or until the trial 10 officially concludes, which -- concludes, whichever 11 occurs first. 12 Do you see that? 13 A. Yes, I do. 14 Q. And that -- does that accurately describe 15 the treatment period of the study? 16 A. It describes the maximum period that 17 patients would -- could receive drug. 18 Q. I'd like to turn your attention to 19 page 30 of 36 -- actually, starting on page 29, 5 -- 20 5.5. It's labeled, Analysis of Clinically 21 Significant UGI Adverse Events. 22 Do you see that? 23 A. Yes, I do. 24 Q. So this -- this section, which is two and</p>	<p style="text-align: center;">28</p> <p>1 A. These were two of other -- of more than 2 two endpoints that would be analyzed. 3 Q. Yeah, but these were the two primary 4 endpoints, correct? 5 A. No, I don't think that says that. 6 Q. Well -- well, it does say right here that 7 these two endpoints will be considered as coprimary, 8 correct? 9 A. Yes. Okay. Yeah. 10 Q. And above that, it says -- 11 A. Yeah. 12 Q. -- two endpoints will be analyzed -- 13 A. Right. 14 Q. -- correct? 15 A. Right. Coprimary for the purposes of -- 16 of the FDA submission, yes. 17 Q. Right. And then it -- it talks about -- 18 if you go down to the bottom, it talks about 19 "symptomatic UGI ulcers." 20 Do you see that, the bottom paragraph? 21 I'm way at the bottom, but -- 22 A. Okay. 23 Q. -- feel free to go -- go through it. 24 Now, at the bottom --</p>



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<p style="text-align: center;">29</p> <p>1 A. Yes --</p> <p>2 Q. At the bottom --</p> <p>3 A. -- I see that.</p> <p>4 Q. I'm sorry. And we -- I'm -- I'm bad at</p> <p>5 that, but we just have to --</p> <p>6 A. I apologize.</p> <p>7 Q. -- make sure we can't talk at the same</p> <p>8 time or --</p> <p>9 A. Agreed.</p> <p>10 Q. -- or she's going to get really angry.</p> <p>11 A. Sorry.</p> <p>12 Q. So symptomatic UGI -- UGI ulcers, those</p> <p>13 were also referred to as GDUs or gastroduodenal</p> <p>14 ulcers; is that correct -- by some people on the</p> <p>15 team?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. And do you call those symptomatic</p> <p>18 ulcers; is that fair?</p> <p>19 A. In -- in this -- in the context of this</p> <p>20 study, yes.</p> <p>21 Q. Okay. Great. And down here at the</p> <p>22 bottom here, it says, "Symptomatic UGI ulcers</p> <p>23 documented by endoscopy or UGI barium X-ray with no</p> <p>24 evidence of perforation, bleeding or obstruction</p>	<p style="text-align: center;">31</p> <p>1 A. Okay.</p> <p>2 Q. So -- so right after the data gets</p> <p>3 unblinded.</p> <p>4 A. Got you.</p> <p>5 Q. Is it accurate that you made some</p> <p>6 internal presentations -- and -- and I'll -- I'll</p> <p>7 break them up -- that you -- you made an internal</p> <p>8 presentation to the Searle SMB in March of 2000</p> <p>9 regarding the results of CLASS?</p> <p>10 A. So, again, things were changing and</p> <p>11 acronyms for different committees and different</p> <p>12 groups were changing.</p> <p>13 So as I recall it, SMB referred to Phil</p> <p>14 Needleman, his direct reports and people he invited</p> <p>15 into a meeting. That would be referred to as an SMB</p> <p>16 meeting.</p> <p>17 So in that context, yes, I do remember</p> <p>18 presenting at that.</p> <p>19 Q. Okay. And let -- let's go a little</p> <p>20 broader.</p> <p>21 A. Yeah.</p> <p>22 Q. I'm getting at, you made a presentation</p> <p>23 of the -- of the data in March of 2000 to the senior</p> <p>24 managers at Searle, which included Dr. Needleman</p>
<p style="text-align: center;">30</p> <p>1 will be categorized and summarized separately"; is</p> <p>2 that accurate?</p> <p>3 A. That's accurate.</p> <p>4 Q. Okay. Now, we can put away Exhibit 77</p> <p>5 for now.</p> <p>6 I just wanted to ask you -- and I want to</p> <p>7 take you -- the -- the -- the time period I'm</p> <p>8 referring to now is the -- the data. I'll represent</p> <p>9 to you that the -- and we can look at some documents</p> <p>10 shortly later, but if this meets with your</p> <p>11 recollection, we can just go from there -- that the</p> <p>12 data was unblinded from the CLASS study on or about</p> <p>13 March 17th of 2000.</p> <p>14 Does that purport with your recollection?</p> <p>15 A. The data was unblinded at that time, yes.</p> <p>16 Q. Okay. And so I'm -- right now I'm</p> <p>17 referring to the period immediately after that, you</p> <p>18 know, the -- the weeks and months, you know --</p> <p>19 A. Okay. Immediate, we're going into</p> <p>20 months?</p> <p>21 Q. Yeah, let's -- let's say that -- that,</p> <p>22 you know, for -- for initial -- for initial</p> <p>23 purposes, we're talk -- I'm talking about March and</p> <p>24 April of 2000.</p>	<p style="text-align: center;">32</p> <p>1 and -- what I'm -- I'm about to ask you is, were</p> <p>2 there any other people senior to Dr. Needleman at</p> <p>3 that meeting?</p> <p>4 A. If we're talking about the same meeting</p> <p>5 that I remember, which was Dr. Needleman and his</p> <p>6 reports and then other people for some other</p> <p>7 departments, I believe, as I recall -- well, I hate</p> <p>8 to say -- I remember Al Heller being there, and I</p> <p>9 don't want to say that Al Heller was senior to</p> <p>10 Dr. Needleman because that might get me in trouble.</p> <p>11 But a high-level person on the commercial side was</p> <p>12 there. Whether he was higher than Dr. Needleman, I</p> <p>13 don't know.</p> <p>14 Q. And who is Al Heller?</p> <p>15 A. I believe he was, like I said, a</p> <p>16 high-level guy on the commercial side, not the</p> <p>17 president, but pretty high up.</p> <p>18 Q. So he'd be like a senior executive vice</p> <p>19 president?</p> <p>20 A. Like it, whatever that means.</p> <p>21 Q. Okay. You don't know his exact title --</p> <p>22 A. No, I don't.</p> <p>23 Q. -- but he was --</p> <p>24 A. I don't.</p>



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<p style="text-align: center;">33</p> <p>1 Q. -- a senior commercial manager?</p> <p>2 A. Right.</p> <p>3 Q. And would he have reported to -- to the</p> <p>4 CEO of Searle at that point in time?</p> <p>5 A. I don't think there was a CEO because we</p> <p>6 were a subsidiary of Monsanto. So the CEO -- there</p> <p>7 was a CEO of Monsanto, and I think the head guy at</p> <p>8 Searle was the president.</p> <p>9 Q. And who was the president at that point?</p> <p>10 A. Dick De Schutter.</p> <p>11 Q. And was he --</p> <p>12 A. If I'm correct that he was called the</p> <p>13 president. I just don't think he was called the</p> <p>14 CEO.</p> <p>15 Q. Okay. And was De Schutter at this</p> <p>16 meeting?</p> <p>17 A. No.</p> <p>18 Q. Did you ever present CLASS to</p> <p>19 De Schutter?</p> <p>20 A. I don't recall ever, you know, seeing him</p> <p>21 in -- in any presentations.</p> <p>22 Q. You just don't know?</p> <p>23 A. But he might have been, because sometimes</p> <p>24 there were -- I presented to big groups. He could</p>	<p style="text-align: center;">35</p> <p>1 So when I'm talking about the entire</p> <p>2 study, I'm simply just referring to the entire</p> <p>3 treatment period without, you know, stopping at a</p> <p>4 certain point in time; is that fair?</p> <p>5 A. Well, I just want to be careful to make</p> <p>6 this -- make it sure. So this was a time-to-event</p> <p>7 study, so the analysis of the time-to-event, the</p> <p>8 final event was presented for the GI complications</p> <p>9 and the symptomatic ulcers.</p> <p>10 Q. Yeah, and there were a couple thousand</p> <p>11 people that took the drugs, in total, for more than</p> <p>12 six months, correct -- or somewhere around there?</p> <p>13 A. For more than six months? I'd have to</p> <p>14 look at the report to see if I would say it was a</p> <p>15 couple thousand.</p> <p>16 Q. But there were some number of people?</p> <p>17 A. Yeah.</p> <p>18 Q. I don't want to get caught up --</p> <p>19 A. Yeah.</p> <p>20 Q. -- in the --</p> <p>21 A. Sure.</p> <p>22 Q. -- number.</p> <p>23 A. Sure.</p> <p>24 Q. Okay. And when you made this</p>
<p style="text-align: center;">34</p> <p>1 have been in the room and I just didn't know he was</p> <p>2 there.</p> <p>3 Q. Okay. So you definitely presented to Al</p> <p>4 Heller and Needleman, and you may have presented to</p> <p>5 De Schutter, you just don't recall?</p> <p>6 A. Right.</p> <p>7 Q. And when you made the presentation in</p> <p>8 late March, would that have included the entire</p> <p>9 study data as opposed to just the 6-month data?</p> <p>10 A. What do you mean by "the entire study</p> <p>11 data"?</p> <p>12 Q. Okay. And I -- and I know that term gets</p> <p>13 confusing, like, because there's lots of things</p> <p>14 you're looking at.</p> <p>15 A. Sure.</p> <p>16 Q. But what I'm talking about is just for</p> <p>17 the GI endpoints, and for right now, we can limit</p> <p>18 that, if you're comfortable with it, to the</p> <p>19 complicated ulcers and then the combination of</p> <p>20 complicated ulcers and the symptomatic ulcers.</p> <p>21 A. Yes.</p> <p>22 Q. You know, and then you could obviously</p> <p>23 look at that, cut off at six months, or you could</p> <p>24 look at it for as long as people were in treatment.</p>	<p style="text-align: center;">36</p> <p>1 presentation to Needleman and Heller and the other</p> <p>2 senior folks at Searle, you didn't limit that</p> <p>3 presentation to just the six months of data,</p> <p>4 correct?</p> <p>5 A. No.</p> <p>6 Q. It was the entire study data?</p> <p>7 A. The -- the entire study data as I defined</p> <p>8 the time-to-event until the last event occurred.</p> <p>9 Q. Correct. So if someone took the drug</p> <p>10 13 months, they would be in that presentation in --</p> <p>11 in the data, if you know?</p> <p>12 A. In the analysis of the ulcer</p> <p>13 complications and the symptomatic ulcer data that we</p> <p>14 presented, yes.</p> <p>15 Q. Okay. And -- and all I'm trying to get</p> <p>16 at is, when you were internally talking about --</p> <p>17 A. Sure.</p> <p>18 Q. -- it with these folks, you didn't limit</p> <p>19 it to just --</p> <p>20 A. Sure.</p> <p>21 Q. -- the six months?</p> <p>22 A. It just gets -- you know, there's</p> <p>23 different definitions for some of this stuff, and I</p> <p>24 want to make sure I'm accurate.</p>



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<p>37</p> <p>1 Q. Yeah. And that -- and that's -- unless</p> <p>2 we say different for the rest of this deposition,</p> <p>3 what I'm -- just for ease and simplicity --</p> <p>4 A. Sure.</p> <p>5 Q. -- when I'm talking about the entire</p> <p>6 study, I'm not talking about every -- the</p> <p>7 26,000 pages.</p> <p>8 A. Yes.</p> <p>9 Q. I'm just talking about the full --</p> <p>10 there -- there's not this exclusion at six months --</p> <p>11 A. Yeah.</p> <p>12 Q. -- it's just all the data for whether</p> <p>13 it's ulcer complications or the combined endpoint of</p> <p>14 symptomatic and complicated.</p> <p>15 A. Okay.</p> <p>16 MR. HOFF: I don't know if that was a question,</p> <p>17 but --</p> <p>18 MR. SAHAM: No, no, that wasn't --</p> <p>19 MR. HOFF: -- I -- I object to it.</p> <p>20 MR. SAHAM: Okay.</p> <p>21 MR. HOFF: I think it would depend on the</p> <p>22 context of your question.</p> <p>23 MR. SAHAM: Okay.</p> <p>24</p>	<p>39</p> <p>1 Q. Okay. And Mr. Fred Hassan was at that</p> <p>2 meeting?</p> <p>3 A. He was at that presentation, yes.</p> <p>4 Q. And was Goran Ando at that presentation?</p> <p>5 A. Yes.</p> <p>6 Q. And was Carrie Cox at that --</p> <p>7 A. Yes.</p> <p>8 Q. -- presentation? Okay.</p> <p>9 A. Yes.</p> <p>10 Q. And when you made the presentation to</p> <p>11 those three individuals and other senior Pharmacia</p> <p>12 managers, did you discuss the entire study data as</p> <p>13 we just defined it?</p> <p>14 A. Well, I don't remember exactly the slide</p> <p>15 set that was used and what was presented, but the</p> <p>16 content that I presented there was consistent with</p> <p>17 the content that I presented at what we earlier</p> <p>18 talked about with the meeting with -- excuse me --</p> <p>19 Dr. Needleman and -- and -- and the higher</p> <p>20 management at Searle.</p> <p>21 So, yes, I would have presented the</p> <p>22 time-to-event for the -- the entire exposure period</p> <p>23 or the -- the last event, as well as the analysis --</p> <p>24 other analyses related to that.</p>
<p>38</p> <p>1 BY MR. SAHAM:</p> <p>2 Q. But -- but I -- just -- just to be clear</p> <p>3 so we can move on --</p> <p>4 MR. HOFF: Right.</p> <p>5 BY MR. SAHAM:</p> <p>6 Q. -- this -- this presentation that you</p> <p>7 made in late -- late March, it wasn't limited to the</p> <p>8 6-month data?</p> <p>9 A. That's correct.</p> <p>10 Q. And shortly after that presentation, is</p> <p>11 it correct that you traveled to New Jersey and made</p> <p>12 a presentation to the senior Pharmacia folks about</p> <p>13 the CLASS data?</p> <p>14 A. Can you tell me what you mean by shortly</p> <p>15 thereafter?</p> <p>16 Q. In early April of 2000 -- and we can look</p> <p>17 at documents --</p> <p>18 A. Yeah, yeah.</p> <p>19 Q. -- approximately early April 2000, did</p> <p>20 you go to New Jersey to make a presentation</p> <p>21 regarding CLASS to the senior Pharmacia executives?</p> <p>22 A. That time frame sounds about right that I</p> <p>23 did go and did present to some higher level people</p> <p>24 from Pharmacia, yes.</p>	<p>40</p> <p>1 Q. Okay. So that presentation was not</p> <p>2 limited to the 6-month data?</p> <p>3 A. It was not.</p> <p>4 Q. And shortly after that time frame, still</p> <p>5 in April of 2000, early April of 2000, let's say the</p> <p>6 first couple weeks, did you make a presentation to</p> <p>7 the operations committee of the joint COX-II</p> <p>8 alliance?</p> <p>9 A. I don't recall.</p> <p>10 Q. Okay. And -- and you recall that Searle</p> <p>11 had an alliance -- a marketing alliance with Pfizer</p> <p>12 for selling and marketing Celebrex; is that correct?</p> <p>13 A. My understanding, it was a codevelopment</p> <p>14 and comarketing alliance.</p> <p>15 Q. Okay. And --</p> <p>16 A. So, yes, that's what I remember.</p> <p>17 Q. And there were certain committees set up</p> <p>18 where Pfizer people could interact with the Searle</p> <p>19 people?</p> <p>20 A. Yes, there were committees.</p> <p>21 Q. And there was an operations committee</p> <p>22 that you were on?</p> <p>23 A. I don't recall. I mean, the -- the term</p> <p>24 operations committee sounds familiar, but I -- I --</p>



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<p>41</p> <p>1 I don't know if I was on it or not, but I -- I know</p> <p>2 the -- the term sounds correct and there were</p> <p>3 committees of people from Pfizer and Searle.</p> <p>4 Q. Okay. And do you recall, in the same</p> <p>5 time frame, making a presentation of the CLASS data</p> <p>6 to one of those committees that had Pfizer folks on</p> <p>7 it?</p> <p>8 A. You know, I gave a lot of presentations</p> <p>9 within the organization during that period to -- to</p> <p>10 inform people about what we had found in the study,</p> <p>11 the complexity of having this codevelopment and</p> <p>12 comarketing thing with Pfizer, you know. So I can't</p> <p>13 remember, well, was it that -- were they there, and</p> <p>14 then you throw on the Pharmacia people?</p> <p>15 And so there were committees and</p> <p>16 meetings, if you will, all over the place that I</p> <p>17 would go to to inform people who wanted or needed to</p> <p>18 know what we had found. But I can -- I can't tell</p> <p>19 you for certain I remember this one and this one and</p> <p>20 this one.</p> <p>21 Q. Okay. But at some point, you recall</p> <p>22 providing the CLASS results or some summary of the</p> <p>23 CLASS results to some of the Pfizer folks?</p> <p>24 A. I know it was presented. I just can't</p>	<p>43</p> <p>1 MR. SAHAM: And for the record, Exhibit 249 is</p> <p>2 a one-page e-mail chain bearing Bates number</p> <p>3 DEFS 01865173. The top e-mail is from George S.</p> <p>4 Geis to various individuals, and it's dated</p> <p>5 March 26, 2000.</p> <p>6 BY MR. SAHAM:</p> <p>7 Q. Is -- is George your middle name or your</p> <p>8 first name?</p> <p>9 A. George is my first name.</p> <p>10 Q. So you sometimes use George, right? I</p> <p>11 guess "use" is a bad word. Sometimes --</p> <p>12 A. My mother does, but nobody else does.</p> <p>13 Q. Sometimes your e-mails say George as</p> <p>14 opposed to Steven?</p> <p>15 A. I know the -- you know, the IT guys do</p> <p>16 what they do, but it -- I go by Steve.</p> <p>17 Q. Okay. But a lot of times, your e-mail</p> <p>18 will say George; is that correct?</p> <p>19 A. So I see. I didn't -- wasn't aware of</p> <p>20 that.</p> <p>21 Q. And I -- my -- my first question is just,</p> <p>22 would -- do you recognize this e-mail?</p> <p>23 A. Let me take a look.</p> <p>24 I don't recognize it, but it's an e-mail</p>
<p>42</p> <p>1 tell you I remember the day, remember who was there.</p> <p>2 I just know it was presented. That's the best I can</p> <p>3 tell you.</p> <p>4 Q. Okay. And when you made the presentation</p> <p>5 or the -- a -- a presentation to the Pfizer folks,</p> <p>6 would that have included the entire study data as</p> <p>7 opposed to just the six months?</p> <p>8 A. The content of all those presentations</p> <p>9 was the same as I described earlier for the -- what</p> <p>10 you had referred to as the SMB. So it would have</p> <p>11 been the time-to-event to the last event and other</p> <p>12 analyses that we did.</p> <p>13 Q. But it wouldn't have been limited to six</p> <p>14 months?</p> <p>15 A. Correct.</p> <p>16 Q. I'm going to show you what I'm marking as</p> <p>17 Plaintiffs' Exhibit 249.</p> <p>18 (WHEREUPON, a certain document was</p> <p>19 marked Plaintiffs' Deposition</p> <p>20 Exhibit No. 249, for identification,</p> <p>21 as of 12/10/2010.)</p> <p>22 BY MR. SAHAM:</p> <p>23 Q. Could you take a look at that document,</p> <p>24 please.</p>	<p>44</p> <p>1 with my name.</p> <p>2 Q. Right. So let me -- let me rephrase the</p> <p>3 question: Is this an e-mail chain you would have</p> <p>4 sent and received on or about March 26, 2000?</p> <p>5 A. Well, based on this paper, it looks like</p> <p>6 I did do it. I don't know -- you said "would have</p> <p>7 sent." It looks like I did it.</p> <p>8 Q. Right. So you -- you received an e-mail</p> <p>9 from Richard Marks on March 24th, and then you sent</p> <p>10 an e-mail to various folks on March 26th --</p> <p>11 A. Yeah.</p> <p>12 Q. -- is that correct?</p> <p>13 A. Yes, that's correct.</p> <p>14 Q. And you did this in the ordinary scope of</p> <p>15 your employment at Pharmacia?</p> <p>16 A. Yes.</p> <p>17 Q. And in your e-mail at the top, you just</p> <p>18 indicate that Phil wants us to present CLASS on</p> <p>19 Wednesday.</p> <p>20 Do you see that?</p> <p>21 A. Yes, I do.</p> <p>22 Q. And you're talking about Phil Needleman?</p> <p>23 A. Yes, I am.</p> <p>24 Q. And is this likely referring to the</p>



<p>45</p> <p>1 presentation you described a few minutes earlier?</p> <p>2 A. It sounds like it's within that time</p> <p>3 frame, and it sort of logically makes sense, yes.</p> <p>4 Q. Okay. I want to show you what's</p> <p>5 previously been marked in this case as Plaintiffs'</p> <p>6 Exhibit 229.</p> <p>7 MR. SAHAM: And, John, what I'm doing here -- I</p> <p>8 don't have the actual one with the stickers, so I'm</p> <p>9 just going to put a new 229 on it. You guys are</p> <p>10 okay with that? It's the same document.</p> <p>11 MR. HOFF: If it's the same document, I don't</p> <p>12 care.</p> <p>13 BY MR. SAHAM:</p> <p>14 Q. Could you please take a look at that</p> <p>15 document, sir.</p> <p>16 MR. SAHAM: And for the record, Exhibit 229</p> <p>17 bears Bates numbers DEFS 01620662 through 728.</p> <p>18 BY MR. SAHAM:</p> <p>19 Q. And then the last page, which maybe if</p> <p>20 you just turn to the last page of the document</p> <p>21 first, because this is something that's going to</p> <p>22 occur over and over again at this deposition.</p> <p>23 The document was produced to us in an</p> <p>24 electronic format in this case, and they indicate</p>	<p>47</p> <p>1 cabinet in the hallway with my name on it --</p> <p>2 Q. Well --</p> <p>3 A. -- I guess.</p> <p>4 MR. HOFF: This is meta data, right?</p> <p>5 MR. SAHAM: Yes. Mr. Hoff --</p> <p>6 MR. HOFF: It would have been somehow</p> <p>7 maintained electronically.</p> <p>8 MR. WEISS: That's the only way you have meta</p> <p>9 data.</p> <p>10 MR. HOFF: Yeah. You wouldn't have meta data</p> <p>11 on a hard copy file --</p> <p>12 THE WITNESS: Okay. Okay. I get it.</p> <p>13 BY MR. SAHAM:</p> <p>14 Q. So it -- so it came from your computers,</p> <p>15 basically, your computer files?</p> <p>16 A. Some file that said it was mine.</p> <p>17 Q. Yes, yes, yes. So I would like you to</p> <p>18 just -- it's a long document. I'd like to briefly</p> <p>19 ask you to look at it and tell me if you can</p> <p>20 identify what this SlideDeck is.</p> <p>21 And it's dated -- on the front, it says</p> <p>22 3/22/00 - CLASS.</p> <p>23 A. Uh-huh. I mean, yes. I see that that's</p> <p>24 what it says.</p>
<p>46</p> <p>1 electronically something called the meta data. I'm</p> <p>2 not sure if you're familiar to that, but these</p> <p>3 documents -- and -- and I'll represent to you, when</p> <p>4 there's a page like that at the end that says, you</p> <p>5 know, your name on it, defendants have represented</p> <p>6 to us in their production of these electronic</p> <p>7 materials that this document came out of your</p> <p>8 custodial files.</p> <p>9 So I'm -- I'm going to represent to you,</p> <p>10 when you look at this document, that this document's</p> <p>11 produced to us out of your custodial files at --</p> <p>12 A. What does that mean --</p> <p>13 Q. I think it means that --</p> <p>14 A. -- my custodial files?</p> <p>15 Q. -- your Pharmacia was -- was bought by</p> <p>16 Pfizer later, but your files, when you worked for</p> <p>17 either Pharmacia or Pfizer, were -- for the purposes</p> <p>18 of this or other litigations, were collected and</p> <p>19 formatted electronically and produced --</p> <p>20 A. Are you saying it came out of a file</p> <p>21 cabinet?</p> <p>22 Q. It could have been your computer. It</p> <p>23 could either be --</p> <p>24 A. But it also could be out of some file</p>	<p>48</p> <p>1 Q. And I -- I just want to ask you if you</p> <p>2 can identify it for me.</p> <p>3 A. Okay. Could you repeat the question?</p> <p>4 Q. Well, my first question is, do you</p> <p>5 recognize this SlideDeck?</p> <p>6 A. Can I give you sort of a bigger picture?</p> <p>7 Because this is a lot of stuff to say I recognize</p> <p>8 the deck. It suggests I'm answering that I</p> <p>9 recognize every slide.</p> <p>10 Q. Right. Let me -- let me ask it</p> <p>11 differently, then --</p> <p>12 A. Please.</p> <p>13 Q. -- and you -- you'll get a chance to</p> <p>14 provide it.</p> <p>15 A. Sure.</p> <p>16 Q. Can you just identify what this is for</p> <p>17 me?</p> <p>18 A. Right. So let me give you some context</p> <p>19 about this. It is common practice -- it was the</p> <p>20 practice within my team, over a period of years,</p> <p>21 that when we would get the results of a trial and</p> <p>22 there would be unblinding, the team would begin to</p> <p>23 look at the analyses in conjunction with the</p> <p>24 statisticians and begin to put slides together on</p>



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<p>49</p> <p>1 how to most effectively present the data.</p> <p>2 As part of that process, they may do</p> <p>3 additional analyses and put those in slides. They</p> <p>4 would also put together slides that would answer</p> <p>5 what they thought would be potential questions about</p> <p>6 the data.</p> <p>7 So it was a way of communicating their</p> <p>8 best ideas among one another was to make slide sets</p> <p>9 and put them together.</p> <p>10 They -- and that really was the -- the</p> <p>11 common practice. So we had slide sets all over the</p> <p>12 place as a way of sharing ideas.</p> <p>13 This looks like this was consistent with</p> <p>14 that as part of a SlideDeck for people sharing ideas</p> <p>15 as to thoughts about the CLASS trial. There's</p> <p>16 design slides. There's some analysis slides.</p> <p>17 There's background slides. There's some slides</p> <p>18 where it's -- it's not complete. It's like somebody</p> <p>19 sort of has an idea and tried to get it on a slide.</p> <p>20 So in that context, I recognize it as</p> <p>21 part of a library of communications about ideas on</p> <p>22 the CLASS data.</p> <p>23 Q. And -- and that's something that would</p> <p>24 have been maintained -- and I'm talking about</p>	<p>51</p> <p>1 electronic files -- or maybe, actually, this one</p> <p>2 doesn't.</p> <p>3 But I would represent to you -- I'm</p> <p>4 sorry, we don't have the meta data, but there's been</p> <p>5 an exhibit entered in this case -- or I'll -- I'll</p> <p>6 strike that.</p> <p>7 I'll represent to you that this came</p> <p>8 from -- like the other one, it's -- for some reason,</p> <p>9 it doesn't have the attachment.</p> <p>10 A. Okay.</p> <p>11 Q. But I think Dr. -- at Dr. Verburg's</p> <p>12 deposition, I'm pretty sure we established that this</p> <p>13 document electronically came from your files. And</p> <p>14 if I'm wrong, I'm sure your counsel will correct me.</p> <p>15 MR. HOFF: I have no idea.</p> <p>16 BY THE WITNESS:</p> <p>17 A. So is this the -- can I make a comment?</p> <p>18 I don't know how Dr. Verburg would know</p> <p>19 what was in my files.</p> <p>20 BY MR. SAHAM:</p> <p>21 Q. Well, no, I think I showed him that</p> <p>22 little -- it's -- maybe it's an exhibit I marked</p> <p>23 separately --</p> <p>24 A. Okay.</p>
<p>50</p> <p>1 Exhibit 229 here -- in the ordinary course of</p> <p>2 business of your team at Pharmacia; is that correct?</p> <p>3 A. The word "maintained" throws me, because</p> <p>4 they would share it. They may give it to me. So</p> <p>5 it's not -- if it was in my file, I could very well</p> <p>6 assume somebody said, here, Steve, here's all of our</p> <p>7 ideas in one big batch.</p> <p>8 Q. So -- so you wouldn't quibble with me</p> <p>9 that this is something that would have been in your</p> <p>10 electronic files from March of 2000 with respect to</p> <p>11 your work at Pharmacia on Celecoxib?</p> <p>12 A. I don't remember it. Could it have been?</p> <p>13 Yeah.</p> <p>14 Q. I want to show you what's previously been</p> <p>15 marked in this case as Plaintiffs' Exhibit 65.</p> <p>16 Could you please take a look at</p> <p>17 Plaintiffs' Exhibit 65.</p> <p>18 And, again, I just want to ask you -- and</p> <p>19 maybe whether you recognize it is not the right</p> <p>20 question, but if you could just identify for me what</p> <p>21 this is.</p> <p>22 And, again, Plaintiffs' Exhibit 65, if</p> <p>23 you look at the last page, it also bears that same</p> <p>24 meta data indication that this came from your</p>	<p>52</p> <p>1 Q. -- that little --</p> <p>2 A. Okay.</p> <p>3 Q. -- thing that looked exactly like the</p> <p>4 other one. And I'm sorry, I didn't bring it --</p> <p>5 A. Okay.</p> <p>6 Q. -- here today, but I'm -- I -- I know</p> <p>7 because I've marked it on --</p> <p>8 A. Okay.</p> <p>9 Q. -- my document that this, like</p> <p>10 Exhibit 249, came out of your electronic files.</p> <p>11 A. Okay.</p> <p>12 Q. And -- and I'd just ask you to -- to --</p> <p>13 to tell me if -- if you can tell me what this is</p> <p>14 generally. Or if it's exactly like 229, you can</p> <p>15 tell me -- tell me that, as well.</p> <p>16 And this document is labeled on the front</p> <p>17 side, CLASS Vignettes, 3/28 version.</p> <p>18 A. Uh-huh.</p> <p>19 Q. And it's a 3-28-00 CLASS Backup. So</p> <p>20 obviously, it's a multipage slide set.</p> <p>21 But I'd -- I'd ask if you -- if you can</p> <p>22 identify what Exhibit 65 is?</p> <p>23 A. I can tell you what it -- I don't -- I</p> <p>24 don't recognize this specifically, but what it looks</p>





<p style="text-align: center;">53</p> <p>1 like is consistent with how I described the previous 2 set of slides, which are a group of slides. It 3 seems to be related to the CLASS trial that would be 4 different ideas that people had about analyses, 5 presentation. 6 They're all labeled Draft, I think, in 7 this. And there's even some -- a couple slides in 8 here that are about, it looks like, a -- a 9 commercial rollout strategy or something. 10 Q. But are these slides that would have been 11 created by you or your team in the ordinary scope of 12 employment at Pharmacia during this period? 13 A. They look like they could have been. I 14 can't say for sure. I mean, I can't say for -- 15 because some -- different people would put together 16 a slide and pass it off and say, here's an idea. 17 Sometimes I put together a slide and put it in a 18 file. 19 Q. And if they were produced from your 20 electronic files, they'd be something that you would 21 have received in this time period in the ordinary 22 scope of your employment? 23 A. To say "received," I would say that's not 24 unlikely. Because sometimes my secretary would</p>	<p style="text-align: center;">55</p> <p>1 (WHEREUPON, a certain document was 2 marked Plaintiffs' Deposition 3 Exhibit No. 250, for identification, 4 as of 12/10/2010.) 5 BY MR. SAHAM: 6 Q. Could you please take a look at 7 Plaintiffs' Exhibit 250. 8 MR. SAHAM: And for the record, 250 bears 9 Bates numbers DEFS 01348832 through 921, and then it 10 does, on the last page, have the printout that 11 indicates that it came from your custodial files. 12 BY THE WITNESS: 13 A. Well, the last page says -- has my name, 14 Ken Verburg and Jim Lefkowitz, so... 15 BY MR. SAHAM: 16 Q. And -- and what that means is that it was 17 produced from multiple peoples -- 18 A. Okay. 19 Q. -- files -- 20 A. Okay. 21 Q. -- including your own. 22 And, again, I -- I'd like you to look at 23 it, and my -- my question to you is just, can you 24 identify for -- for me what this is? And if it's</p>
<p style="text-align: center;">54</p> <p>1 receive stuff from people and she'd put it into a 2 file. 3 Q. But these are documents, they're not -- 4 this isn't like a personal e-mail or something, this 5 is a business document; is that fair to say? 6 A. I'm reluctant to call it a document as 7 though -- that this was put together as one big set 8 at one time. This could have been the amalgamation 9 of, 15 slides are passed off on day 5, 20 more were 10 paid off -- you know, play -- you know, passed off 11 as they got more ideas. 12 So this could have been the amalgamation 13 of several sets of ideas in the form of slides 14 passed off and ended up in my -- my file. 15 Q. And it would be passed to you by your 16 Celecoxib team members? 17 A. That would -- that would not be out of 18 the normal course of practice, correct. I can't 19 just say I know that this was. 20 Q. Okay. I want to show you what I'm 21 marking as Plaintiffs' Exhibit 250. 22 23 24</p>	<p style="text-align: center;">56</p> <p>1 the same as what you were talking about before, you 2 can say that, as well. 3 And it's labeled on the front, 4 3/23/00 testing.ppt. 5 A. Uh-huh, okay. Yes, I -- I see that 6 that's what it says on the front. 7 Can I ask you a question? Is -- are some 8 of these -- it looks like -- is that because they 9 didn't print right, or is this -- can you say that 10 this is really what was in the file? 11 Q. It could have been a printing -- you 12 know, that foggy one. It could be -- you know, it's 13 ten years ago -- whether the way they were -- 14 A. Okay. 15 Q. -- captured when they were presented to 16 us. 17 A. Okay. 18 Q. But I couldn't say for certain that -- 19 A. Because some of it is, you know, very 20 difficult to look at. 21 Q. Looking at -- looking at all -- that all 22 the copies have that, I would have to guess that 23 that's the way it was produced. 24 A. Okay. Could you repeat the question?</p>



<p style="text-align: center;">57</p> <p>1 Q. Yeah. I'm just asking if you could tell 2 me what -- what this is, Exhibit 250, I'm referring 3 to?</p> <p>4 A. These -- these are hard copies of what 5 appear to be slides, all labeled Draft, that are -- 6 appear to be related to the CLASS study in some way, 7 which would have been a way of sharing ideas 8 consistent with what I talked about earlier, about 9 the team putting ideas together, about the study, 10 about the analysis, about the results, and shared in 11 the form of -- of draft slides.</p> <p>12 Q. And -- and these would have been in 13 your -- strike that.</p> <p>14 This would have been something that you 15 received during March of 2000 in your employment at 16 Pharmacia?</p> <p>17 A. I don't remember seeing it, but it -- it 18 looks like something I could have received, because 19 this was the process with which the team shared 20 ideas back and forth, was in the form of slides such 21 as these.</p> <p>22 Q. I want to show you what's previously been 23 marked in this case as Plaintiffs' Exhibit 220. 24 Could you please take a look at</p>	<p style="text-align: center;">59</p> <p>1 A. Well, like I said earlier, at this time, 2 which would have been April 5th, I'm not sure who I 3 would say was head of R&amp;D.</p> <p>4 Q. But it was either --</p> <p>5 A. Anywhere.</p> <p>6 Q. It was either Needleman or Ando, correct?</p> <p>7 A. Yeah. Yes, correct.</p> <p>8 Q. So they were either coheads or one was 9 the other's boss?</p> <p>10 A. I think that sounds about correct.</p> <p>11 Q. Okay. And this appears to be comments 12 that Dr. Ando shared with Dr. Friedman and 13 Dr. Needleman with respect to your presentation 14 regarding CLASS that had occurred in early April; is 15 that fair to say?</p> <p>16 A. Yeah. The part that's from Dr. Ando -- 17 because this is a chain of e-mails, but the part 18 from Dr. Ando to Drs. Friedman and Needleman are his 19 comments on the presentation and thoughts.</p> <p>20 Q. And this would help place the date of 21 that presentation as, at least, some point before 22 April 5th of 2000; is that correct?</p> <p>23 A. Yeah, that appears to be correct.</p> <p>24 Q. And was it your --</p>
<p style="text-align: center;">58</p> <p>1 Plaintiffs' Exhibit 220.</p> <p>2 MR. SAHAM: And for the record, 220 is a 3 two-page e-mail chain that -- the second from top 4 e-mail was -- with the rest of the chain below it, 5 was forwarded to you, apparently, by Dr. Friedman 6 who received it, along with Dr. Needleman, from 7 Dr. Ando on April 5th, 2000. It appears to have 8 been forwarded to you on that same date.</p> <p>9 BY MR. SAHAM:</p> <p>10 Q. And I'd ask you if you recognize this 11 document?</p> <p>12 A. Could you repeat the question?</p> <p>13 Q. Well, my first question, is this an 14 e-mail that you would have received in the ordinary 15 course of your employment at Pharmacia on or about 16 April 5th, 2000?</p> <p>17 A. According to this piece of paper, it came 18 to me through Michael Friedman, yes, but I don't 19 recognize this.</p> <p>20 Q. Okay. And -- and Dr. Friedman was your 21 boss at this time?</p> <p>22 A. Correct.</p> <p>23 Q. And Dr. Ando was the head and R&amp;D -- head 24 of R&amp;D at Pharmacia?</p>	<p style="text-align: center;">60</p> <p>1 A. Let me -- when you say "that 2 presentation," can I make -- make it clear?</p> <p>3 Q. Sure. I'm talking --</p> <p>4 A. Somehow Dr. Ando had this presented to 5 him in order for him to make comments. If you're 6 referring to "that presentation" being the one we 7 talked about earlier with Carrie Cox, et cetera, you 8 know, I can't say for sure that that's the only 9 place Goran Ando would have heard this.</p> <p>10 Q. Okay.</p> <p>11 A. So I just want to be -- I just want to be 12 precise about this, that I don't remember.</p> <p>13 Q. Appreciate that.</p> <p>14 But you know what you presented to Cox, 15 Hassan and Ando in early April, correct?</p> <p>16 A. Yes.</p> <p>17 Q. And you -- there also may have been 18 additional presentations or information provided to 19 Dr. Ando, but you're just not certain of that?</p> <p>20 A. Correct.</p> <p>21 Q. And was it your practice in this 22 period -- and I'm -- I'm really specifically talking 23 about the presentation to Needleman and his group 24 and the presentation to Hassan, Cox and Ando that</p>



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<p>61</p> <p>1 we've discussed earlier.</p> <p>2 Was it your practice to use PowerPoint</p> <p>3 slides at those two presentations -- or -- or strike</p> <p>4 that. Let me ask it in two parts.</p> <p>5 Was it your practice to use PowerPoint</p> <p>6 slides when doing this type of presentation</p> <p>7 regarding, you know, study data?</p> <p>8 A. We used a combination of PowerPoint -- I</p> <p>9 personally -- so I'm only going to speak for me. I</p> <p>10 personally found using PowerPoint slides as very --</p> <p>11 a way to -- you know, it -- give the presentation</p> <p>12 effectively, but we also used -- what do you call</p> <p>13 those things? -- flip charts --</p> <p>14 Q. Okay.</p> <p>15 A. -- in -- in the course of it.</p> <p>16 Q. So in 2000 when you'd make a presentation</p> <p>17 about a trial, you'd use PowerPoint and flip charts</p> <p>18 generally?</p> <p>19 A. Generally, yes. I would, yes.</p> <p>20 Q. And do you recall -- and I'm going to</p> <p>21 first refer you to the presentation to Dr. Needleman</p> <p>22 and his group at Searle.</p> <p>23 Do you recall using PowerPoint at that</p> <p>24 presentation?</p>	<p>63</p> <p>1 Q. And this came out of Aimee Burr's</p> <p>2 custodial file, which I believe you said was one of</p> <p>3 your reports?</p> <p>4 Burr worked for you at that period,</p> <p>5 right?</p> <p>6 A. Aimee Burr did not report directly to me,</p> <p>7 but Aimee Burr was on, if you will, the arthritis,</p> <p>8 inflammation and pain team and worked on the CLASS</p> <p>9 trial.</p> <p>10 Q. And -- and this set of slides is -- is</p> <p>11 the draft CLASS Celecoxib long-term arthritis safety</p> <p>12 study, 4300-CLASS.</p> <p>13 Do you know -- well, strike that.</p> <p>14 Could some of these slides been used in</p> <p>15 your presentation to Dr. Hassan and Dr. Ando and</p> <p>16 Ms. -- Ms. Cox?</p> <p>17 A. If they came out of Aimee's custodial</p> <p>18 file, no, because I wouldn't have taken something</p> <p>19 out of someone else's custodial file.</p> <p>20 Q. Okay. And with respect to the other</p> <p>21 three slide decks we looked at earlier which we've</p> <p>22 marked -- you know, that are all dated March that</p> <p>23 we've marked as 250, 65 --</p> <p>24 A. I'm sorry, I want to keep up with you.</p>
<p>62</p> <p>1 A. So if we're referring back to what you</p> <p>2 talked about as the SMB meeting --</p> <p>3 Q. Correct.</p> <p>4 A. -- yes, it would have been PowerPoint and</p> <p>5 flip chart.</p> <p>6 Q. And now I want to refer specifically to</p> <p>7 the Hassan, Cox, Ando meeting in --</p> <p>8 A. Uh-huh.</p> <p>9 Q. -- early April.</p> <p>10 Do you recall using PowerPoint at that</p> <p>11 presentation?</p> <p>12 A. I do --</p> <p>13 Q. Okay.</p> <p>14 A. -- and flip chart.</p> <p>15 Q. Okay. So you did use PowerPoint at both</p> <p>16 of those meetings?</p> <p>17 A. Yes.</p> <p>18 Q. I want to show you what's been marked</p> <p>19 previously as Exhibit 221.</p> <p>20 Could you please take a look at that</p> <p>21 document?</p> <p>22 MR. SAHAM: And, again, 221 bears Bates numbers</p> <p>23 DEFS 01216542 through 657.</p> <p>24 BY MR. SAHAM:</p>	<p>64</p> <p>1 Q. Yeah. Yeah, I'm sorry. It's exhibits --</p> <p>2 the -- the three big decks.</p> <p>3 A. Right.</p> <p>4 Q. 250, 65 and 229, those all came out of</p> <p>5 your files.</p> <p>6 Is it possible that you borrowed some of</p> <p>7 those slides or used some of those slides in your</p> <p>8 presentation to Dr. Hassan in early April -- or</p> <p>9 Mr. Hassan in early April?</p> <p>10 A. I don't remember.</p> <p>11 Q. But are those the types of slides that</p> <p>12 you would have used -- at least some of those?</p> <p>13 A. The formats look like what we would have</p> <p>14 used, but I -- I -- I don't remember.</p> <p>15 Q. And -- and these decks are certainly</p> <p>16 communicating the CLASS results, correct?</p> <p>17 A. They're communicating early thoughts</p> <p>18 about the CLASS study, yes.</p> <p>19 Q. Okay. I want to show you what's</p> <p>20 previously been marked in this case as Plaintiffs'</p> <p>21 Exhibit 84.</p> <p>22 Could you please take a look at that</p> <p>23 document?</p> <p>24 MR. SAHAM: And for the record, Plaintiffs'</p>





<p style="text-align: center;">65</p> <p>1 Exhibit 84 came out of your custodial files, and 2 it's labeled April 7, 2000 Celebrex Long-Term 3 Arthritis Safety Study, and it says Rollout 4 Strategy. It's a little difficult to read, but... 5 And it bears Bates numbers DEFS 01427984 through 6 008. 7 BY MR. SAHAM: 8 Q. Okay. And then this, again, came out of 9 your electronic files, and I'd ask if you could 10 identify what it is? 11 A. No, I cannot. 12 Q. Okay. Does it, again, seem to be 13 something similar to what you referred to with 14 respect to the other slide decks? 15 A. No. This is completely different. 16 Q. Okay. But you're not -- you're not sure 17 what it is? 18 A. I am not. 19 Q. Does it appear to be a presentation that 20 you made? 21 A. I would say absolutely no, it's not a 22 presentation I would have made. 23 Q. But you're not disputing that it came out 24 of your electronic file?</p>	<p style="text-align: center;">67</p> <p>1 Q. Did you help him prepare it, or your 2 team? 3 A. Yes. 4 Q. Okay. And so you had input into the 5 slides that he provided or used? 6 A. Yes. 7 Q. Okay. And this -- this slide here is 8 labeled Issues Generated from ACP? 9 A. That's what it says. 10 Q. Okay. But you're not really sure what 11 it's referring to? 12 A. No. 13 Q. Okay. And then I'd like you to turn to 14 the page 997, so a couple more pages further. 15 A. Uh-huh -- 16 Q. And it says media -- 17 A. -- yes. 18 Q. -- and analyst post-ACP? 19 Do you see that? 20 A. I do. 21 Q. And it says, press release, release 22 issued Monday, April 17th a.m. 23 Do you see that? 24 A. I do.</p>
<p style="text-align: center;">66</p> <p>1 A. Well, whoever wrote this page that said 2 custodian, I -- if they got it right, then it came 3 out of my file. 4 Q. Okay. And I'd like to refer you to two 5 specific pages of this SlideDeck. The -- there's 6 those little Bates numbers in the bottom right-hand 7 corner. If you can go to the last three that are 8 numbered 995. I'm referring to the last three 9 Bates numbers. 10 A. Uh-huh. 11 Q. And this is -- it -- it had an Issues 12 Generated from ACP? 13 A. Yes. 14 Q. Is -- ACP, is that referring to the 15 American College of Physicians? 16 A. I don't know for sure. 17 Q. But do you recall rolling out the data at 18 the ACP? Was that one of the first places that it 19 was talked about, the CLASS results? 20 A. A presentation on CLASS was given at ACP. 21 Q. And was that given by Dr. Silverstein? 22 A. Yes, it was. 23 Q. Did you participate in that presentation? 24 A. I did not give the presentation.</p>	<p style="text-align: center;">68</p> <p>1 Q. Do you recollect that the first press 2 release that Pharmacia issued with respect to the 3 CLASS results was issued on April 17th? 4 A. I don't recall. 5 But -- but could I point something out 6 that's sort of thrown me about this whole set? 7 Q. Sure. 8 A. It identifies ACP was on 4/15, but the 9 date on some of these slides is April 7th. 10 Q. Right. So does this appear to be maybe 11 like a draft or something that may -- was 12 anticipated possibly being used, or you don't know? 13 A. I don't know, or somebody mislabeled 14 stuff -- 15 Q. Okay. 16 A. -- or it's just wrong. 17 Q. And in looking at this 997 page, another 18 thing it says is Media teleconference, 10:00 a.m. 19 Monday morning, Silverstein, Simon, Whelton, medical 20 spokespersons. 21 Do you recall being on a teleconference 22 with -- with the media on or about April 17th? 23 A. I do not. 24 Q. But you recall speaking publicly about</p>



<p style="text-align: center;">69</p> <p>1 the CLASS trial?</p> <p>2 A. I didn't give the presentation at ACP --</p> <p>3 Q. But --</p> <p>4 A. -- no.</p> <p>5 Q. -- but do you recall being on conference</p> <p>6 calls with reporters about the CLASS study?</p> <p>7 A. At some point. I don't -- I don't -- I</p> <p>8 don't believe it was at this time.</p> <p>9 Q. Okay. And I'm not trying to refer to</p> <p>10 ACP, I'm just generally saying --</p> <p>11 A. Right. But this -- so if we are talking</p> <p>12 about right around ACP and very early, I do not</p> <p>13 re- -- recall talking to reporters at all.</p> <p>14 Q. And then the -- the last two bullet</p> <p>15 points say, Coordinated international distribution</p> <p>16 of press release, analyst briefing Monday,</p> <p>17 April 17th, a.m.</p> <p>18 Do you see that?</p> <p>19 A. I do see that.</p> <p>20 Q. Do you recall there being briefings of</p> <p>21 securities analysts in the April time frame?</p> <p>22 A. I don't recall any of this.</p> <p>23 Q. Okay. But you -- again, you don't</p> <p>24 dispute that this was in your electronic files?</p>	<p style="text-align: center;">71</p> <p>1 A. She's an employee at Searle.</p> <p>2 Q. And what -- do you know what their jobs</p> <p>3 were, generally?</p> <p>4 A. They were on the commercial side -- what</p> <p>5 I call the commercial side of the organization.</p> <p>6 Q. Okay. And do you know why this document</p> <p>7 would have been in your electronic files?</p> <p>8 A. Other than I received tons of e-mails</p> <p>9 with attachments from different parts of the</p> <p>10 organization.</p> <p>11 Q. Okay. And this is a document you would</p> <p>12 have received in your capacity in working for that</p> <p>13 organization, whether it's Searle or Pharmacia at</p> <p>14 this point in time?</p> <p>15 A. Quite frankly, I'm surprised because this</p> <p>16 is not something I recognize, like, at all. So</p> <p>17 I'm -- it may have come through, but it's not</p> <p>18 something I would say, yes, I used to see these</p> <p>19 kinds of documents. I --</p> <p>20 Q. And, again --</p> <p>21 A. -- I don't even recognize the font on</p> <p>22 this.</p> <p>23 Q. Okay. And Al Heller who's a cc, you</p> <p>24 identified him earlier as being a senior commercial</p>
<p style="text-align: center;">70</p> <p>1 A. I don't dispute that the last page says</p> <p>2 that.</p> <p>3 Q. I want to show you what I'm marking as</p> <p>4 Plaintiffs' Exhibit 251.</p> <p>5 (WHEREUPON, a certain document was</p> <p>6 marked Plaintiffs' Deposition</p> <p>7 Exhibit No. 251, for identification,</p> <p>8 as of 12/10/2010.)</p> <p>9 BY MR. SAHAM:</p> <p>10 Q. Could you please take a look at that</p> <p>11 document.</p> <p>12 MR. SAHAM: And, again, this document</p> <p>13 indicates -- was indicated in the meta data that it</p> <p>14 came from your electronic files. It bears</p> <p>15 Bates numbers DEFS 00115007 through 019, and it's</p> <p>16 dated April 7th, 2000. It's from Kerstin Schultz.</p> <p>17 You're not listed as a cc -- or, no, sorry, it's to</p> <p>18 Kerstin Schultz from Michael M. Cunnington. And it</p> <p>19 says March Management Report.</p> <p>20 BY MR. SAHAM:</p> <p>21 Q. Do you know who Michael M. Cunnington is?</p> <p>22 A. Mike Cunning- -- Michael Cunnington was</p> <p>23 an employee at Searle.</p> <p>24 Q. Okay. And who's Kerstin Schultz?</p>	<p style="text-align: center;">72</p> <p>1 guy at Searle?</p> <p>2 A. Where is Al Heller cc'd on this?</p> <p>3 Q. He's, like, the sixth down.</p> <p>4 A. Oh, yes. Correct, yes.</p> <p>5 Q. And what about Joe Papa, was he a senior</p> <p>6 commercial guy?</p> <p>7 A. I -- I don't know what his role was. I</p> <p>8 know he was on commercial and he was at Searle.</p> <p>9 Q. And then looking -- again, I just want to</p> <p>10 turn you to the last three Bates numbers, 011. Up</p> <p>11 at the top, there's a bullet point.</p> <p>12 A. I'm on that page.</p> <p>13 Q. The top bullet point says, Results from</p> <p>14 Celebrex long-term safety study are under analysis.</p> <p>15 Communication of results and commercialization plans</p> <p>16 will be finalized with senior management on</p> <p>17 April 7th.</p> <p>18 Do you recall being involved in that</p> <p>19 process of the finalization of the communication of</p> <p>20 the results of CLASS?</p> <p>21 A. I'm -- I'm not sure what you mean by the</p> <p>22 "finalization of the communication."</p> <p>23 So prior to this time, we were</p> <p>24 communicating internally to -- to management. So I</p>



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<p style="text-align: center;">73</p> <p>1 don't know what this is referring to. I don't know 2 what they're even referring to here. 3 Q. But at some point in April, Pharmacia and 4 Pfizer started communicating about the results of 5 CLASS publicly; is that correct? 6 MR. HOFF: Objection to form. 7 BY THE WITNESS: 8 A. Could you repeat the question? 9 BY MR. SAHAM: 10 Q. Some point in April of 2000, Pharmacia 11 and Pfizer started publicly communicating about the 12 results of the CLASS trial; is that -- 13 MR. HOFF: Objection -- 14 BY MR. SAHAM: 15 Q. -- fair to say? 16 MR. HOFF: Objection to form. 17 BY THE WITNESS: 18 A. In April, Fred Silverstein gave a 19 presentation at ACP, and I think it was on 20 April 15th. That's all I know about the first 21 external presentation of the CLASS data, meaning, 22 external presentation to the public. 23 MR. SAHAM: Okay. We need to change the tape 24 now, so we'll take a quick --</p>	<p style="text-align: center;">75</p> <p>1 A. I don't recall if there was a contract 2 about payment or not. 3 Q. Okay. You just didn't deal with that 4 part of it? 5 A. I -- I don't recall dealing with that 6 part of it. 7 Q. Do -- do you think he was working on the 8 project for free? 9 A. I -- I can't recall. I don't know how 10 that worked. 11 Q. Okay. And when he was speaking at ACP, 12 was he asked to do that by Pharmacia as part of his 13 role as a consultant? 14 A. I'd have to remember how it transpired. 15 I -- I don't recall exactly how the -- the 16 invitation was made and how it -- how it came out. 17 Q. And earlier, we talked about, you know, 18 various presentations you had made to Pfizer people 19 about CLASS results? 20 A. Well, I know we had a conversation about 21 it, but I believe I said I don't remember giving 22 presentations to Pfizer people. 23 Q. Oh, you don't remember any presentations 24 to Pfizer?</p>
<p style="text-align: center;">74</p> <p>1 THE WITNESS: Okay. 2 MR. SAHAM: -- break. 3 THE WITNESS: Sure. 4 THE VIDEOGRAPHER: Going off the video record 5 at 10:27 a.m. 6 This is the end of Tape No. 1. 7 (WHEREUPON, a short recess was 8 had.) 9 THE VIDEOGRAPHER: Going back on the video 10 record at 10:42 a.m. 11 This is two beginning of Tape No. 2. 12 BY MR. SAHAM: 13 Q. Dr. Geis, you -- you talked about 14 Dr. Silverstein who made the presentation at ACP a 15 minute ago. 16 Remember that? 17 A. I do. 18 Q. And Dr. Silverstein was a paid consultant 19 of Pharmacia; is that correct? 20 A. I can't re- -- I can't recall about 21 contracts being paid or, you know, if he was paid or 22 not in what capacity, but he was a consultant to us. 23 Q. You just don't know how much money he was 24 paid?</p>	<p style="text-align: center;">76</p> <p>1 A. I don't re- -- no, I don't remember 2 presenting to Pfizer. I don't remember either way. 3 Q. Okay. 4 A. I'm not saying I didn't. I know there -- 5 there were these meetings, but I don't remember 6 presenting at them. 7 Q. Okay. I'm going to show you what's been 8 marked as Plaintiffs' Exhibit 162 previously. 9 Could you please take a look at 10 Plaintiffs' Exhibit 162? 11 MR. SAHAM: And for the record, Exhibit 162 12 bears Bates numbers DEFS 00170973 through 976. And 13 it's an e-mail chain that attaches the Searle Pfizer 14 operations committee April 6, 2000 video conference 15 minutes. 16 And the e-mail indicates that it was sent 17 to you, Ethan Weiner, Gary Jortner, Guy Buckland, 18 Joe Feczko and others, on or about April 12th, 2000. 19 BY MR. SAHAM: 20 Q. Would you agree with me this is an e-mail 21 you would have received on or about April 12th, 2000 22 in your capacity as an employee of Pharmacia? 23 A. Hang on. Let me just look at it real 24 quick.</p>



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<p>77</p> <p>1 I don't remember this either way.</p> <p>2 Q. Okay. And -- but you have no reason to</p> <p>3 believe you didn't receive this e-mail in the</p> <p>4 ordinary course of your employment at Pharmacia?</p> <p>5 A. I mean, it says it was addressed to me.</p> <p>6 So I don't know either way, but it was addressed to</p> <p>7 me.</p> <p>8 Q. Okay. And then if you look at the</p> <p>9 Searle -- the second page -- well, it's the second</p> <p>10 through fourth page of the document. It says it's</p> <p>11 the Videoconference Minutes from April 6, 2000,</p> <p>12 Searle Pfizer Operations Committee.</p> <p>13 Do you see that?</p> <p>14 A. I do.</p> <p>15 Q. And you -- does this refresh your</p> <p>16 recollection that you would have been on that</p> <p>17 committee?</p> <p>18 A. No, it does not.</p> <p>19 Q. Okay. And do you know who Dr. Feczko is?</p> <p>20 A. Dr. Feczko was an employee at Pfizer.</p> <p>21 Q. And was he a senior medical officer</p> <p>22 there -- chief medical officer?</p> <p>23 A. I don't know if that's what his role was.</p> <p>24 Q. Was he a senior executive at Pfizer?</p>	<p>79</p> <p>1 Does this -- do these minutes indicate</p> <p>2 that you presented a summary analysis on April 6th,</p> <p>3 2000?</p> <p>4 A. It says, "Summary analysis presented</p> <p>5 (Geis)."</p> <p>6 I don't know that that means I presented.</p> <p>7 I don't know what it means.</p> <p>8 Q. Okay. But you -- you recall making</p> <p>9 presentations internally, you just don't recall</p> <p>10 whether you made one on April 6th to this ops</p> <p>11 committee?</p> <p>12 A. That's correct.</p> <p>13 Q. Okay. But you're not disputing that you</p> <p>14 did make one, you just don't know one way or the</p> <p>15 other?</p> <p>16 A. And that -- yeah, I don't know -- I don't</p> <p>17 remember either way.</p> <p>18 Q. Okay. Thank you, sir.</p> <p>19 I want to show you what I'm marking as</p> <p>20 Plaintiffs' Exhibit 252.</p> <p>21 (WHEREUPON, a certain document was</p> <p>22 marked Plaintiffs' Deposition</p> <p>23 Exhibit No. 252, for identification,</p> <p>24 as of 12/10/2010.)</p>
<p>78</p> <p>1 A. I don't know.</p> <p>2 Q. Do you recall being any -- at any</p> <p>3 meetings where the CLASS results were discussed with</p> <p>4 Mr. Feczko?</p> <p>5 A. Around this time --</p> <p>6 Q. Well, first --</p> <p>7 A. -- this time period?</p> <p>8 Q. -- just at all, do you remember being at</p> <p>9 any meetings where he -- the results were discussed</p> <p>10 with him?</p> <p>11 A. No, I don't.</p> <p>12 Q. Okay.</p> <p>13 A. No, I don't.</p> <p>14 Q. And do you know who Montwill is,</p> <p>15 M-o-n-t-w-i-l-l?</p> <p>16 A. Yeah. I believe -- I think his name was</p> <p>17 Richard Montwill. I -- as I recall, he was an</p> <p>18 employee at Searle on the commercial side.</p> <p>19 Q. Okay. And if you look at the second page</p> <p>20 of the document, the April 6, 2000 Videoconference</p> <p>21 Minutes, under 3, it says Priority Issues Update,</p> <p>22 and it says T1 Celebrex CLASS Action. And then</p> <p>23 under that, it says, summary analysis presented by</p> <p>24 Geis.</p>	<p>80</p> <p>1 BY MR. SAHAM:</p> <p>2 Q. Could you please take a look at that</p> <p>3 document.</p> <p>4 MR. SAHAM: And for the record, Plaintiffs'</p> <p>5 Exhibit 252 bears Bates numbers DEFS 00392275</p> <p>6 through 317. And it's a one-page e-mail that</p> <p>7 attaches a set of slides. The middle e-mail on the</p> <p>8 first page is from George Geis to Leland Loose,</p> <p>9 dated April 17th of 2000.</p> <p>10 And then above that is an e-mail chain</p> <p>11 from Leland Loose to Ethan Weiner and others that</p> <p>12 says, "These are the final slides shown at the ACP</p> <p>13 meeting."</p> <p>14 And then starting at page 2 of the</p> <p>15 document, there's a set of 42 slides.</p> <p>16 And I'd ask you generally if you could</p> <p>17 iden- -- identify this e-mail and presentation for</p> <p>18 me?</p> <p>19 Is it correct that these are the slides</p> <p>20 utilized by Dr. Silverstein at his ACP presentation</p> <p>21 on April 15th, 2000?</p> <p>22 A. I can't say I recall specifically that</p> <p>23 these are all the slides. And by the e-mail, it</p> <p>24 identifies them as such, but I can't say I remember</p>



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<p>81</p> <p>1 every slide in here. And some of them have -- and</p> <p>2 it may have been the way they were printed -- errors</p> <p>3 on them. So I can't imagine a slide that looked</p> <p>4 like this he presented, so...</p> <p>5 Q. But you wrote to Dr. Loose on April 17,</p> <p>6 2000, "Attached are the slides"?</p> <p>7 A. I -- I agree that's what it says, but I</p> <p>8 don't recall writing this e-mail.</p> <p>9 Q. But you don't dispute that you wrote to</p> <p>10 Leland Loose on April 17, 2000, "I think it went</p> <p>11 quite well on Saturday night. Attached are the</p> <p>12 slides"?</p> <p>13 A. As I said, I don't recall this e-mail. I</p> <p>14 know what the e-mail says, and it did come --</p> <p>15 come -- come from me, but I'm just saying I don't</p> <p>16 remember writing it.</p> <p>17 Q. And you say it came from -- but you agree</p> <p>18 with me it came from you, correct?</p> <p>19 A. Yes.</p> <p>20 Q. And you sent it in the capacity as an</p> <p>21 employee at Pharmacia to Dr. Loose in his capacity</p> <p>22 as an employee at Pfizer on or about April 17, 2000?</p> <p>23 A. That's what this looks like, yes.</p> <p>24 Q. And then Dr. Loose forwards the e-mail to</p>	<p>83</p> <p>1 A. I reviewed, just sort of in general, my</p> <p>2 understanding and my -- my recollection of the press</p> <p>3 release process, if I had seen the press release or</p> <p>4 understood it.</p> <p>5 I subsequently reached out to members of</p> <p>6 the PR team from Searle, specifically Sally Benjamin</p> <p>7 Young and Claudia Kovitz, and asked some questions</p> <p>8 of them to prepare myself.</p> <p>9 Q. Okay. And speaking of the April 17th</p> <p>10 press release, who drafted that press release? Do</p> <p>11 you know?</p> <p>12 A. I don't know.</p> <p>13 Q. Okay. Who participated in the approval</p> <p>14 process for that press release?</p> <p>15 A. I don't know. You mean specific names?</p> <p>16 I don't know.</p> <p>17 Q. Okay. But you saw it in advance of it --</p> <p>18 it going out, correct?</p> <p>19 A. No, I don't recall having seen it.</p> <p>20 Q. It was e-mailed to you, correct?</p> <p>21 A. I don't know that.</p> <p>22 Q. Do you recall, in your preparations for</p> <p>23 the 30(b)(6) deposition, reviewing draft e-mails</p> <p>24 from April 7th, April 11th and April 14th of 2000</p>
<p>82</p> <p>1 Dr. Weiner, Dr. Wahba and others and says, "These</p> <p>2 are the final slides shown at the ACP meeting,"</p> <p>3 correct?</p> <p>4 A. That's what the e-mail says, yes.</p> <p>5 Q. Okay. I want to show you -- well, before</p> <p>6 I do that, do you recall or -- or do -- do you</p> <p>7 understand that you've been designated by the</p> <p>8 defendants, or specifically the defendant Pharmacia,</p> <p>9 as what's called a 30(b)(6) witness?</p> <p>10 A. Yes, I do.</p> <p>11 Q. And one of the topics that you've been</p> <p>12 designated to testify about on behalf of Pharmacia</p> <p>13 is the press release that was issued by Pharmacia on</p> <p>14 April 17th, 2000; is that correct?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. So we're going to talk about that</p> <p>17 now. And you understand that your testimony in this</p> <p>18 regard is being offered both in a personal capacity</p> <p>19 as well as a representative of Pharmacia, correct?</p> <p>20 A. Yes, I understand that.</p> <p>21 Q. Okay. And did you do certain things to</p> <p>22 prepare for that testimony?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. And what did you do?</p>	<p>84</p> <p>1 that contained drafts of the press release?</p> <p>2 A. No, I don't.</p> <p>3 Q. Okay. So you didn't do that in preparing</p> <p>4 for today's deposition?</p> <p>5 A. I don't recall having done it.</p> <p>6 Q. Okay. Do you under- -- do you recall</p> <p>7 there being, at Searle, something called the</p> <p>8 regulatory affairs committee?</p> <p>9 A. If that refers to RAC, yes.</p> <p>10 Q. And what is RAC?</p> <p>11 A. So my understanding is, RAC was a team</p> <p>12 with representatives from a variety of functional</p> <p>13 areas who re- -- who reviewed information such as</p> <p>14 advertisement, press releases, things that went out</p> <p>15 to the public, and they approved them to be used.</p> <p>16 Q. And did they do so -- and they -- strike</p> <p>17 that.</p> <p>18 Did they do that as employees of</p> <p>19 Pharmacia or Searle?</p> <p>20 A. Well -- so RAC was specific, in my</p> <p>21 recollection, for Searle. That was the terminology</p> <p>22 for Searle. And they did that on behalf of Searle,</p> <p>23 is my understanding.</p> <p>24 Q. And do you know who was on that committee</p>



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<p style="text-align: center;">85</p> <p>1 or on the RAC?</p> <p>2 A. Some of the members that I can tell you</p> <p>3 that I know. I don't know all of them.</p> <p>4 Q. Tell me who you recall.</p> <p>5 A. Sure. Catherine Wertjes, Winifred</p> <p>6 Begley, Jerry Prahl, those are the ones that I</p> <p>7 remember by name.</p> <p>8 Q. Okay. I want to show you what's</p> <p>9 previously been marked in this case as</p> <p>10 Plaintiffs' Exhibit 86.</p> <p>11 Could you please take a look at</p> <p>12 Plaintiffs' Exhibit 86, which for the record, is an</p> <p>13 April 11 e-mail chain which attaches a fax sheet and</p> <p>14 a draft of the April 17th, 2000 press release. It</p> <p>15 bears Bates numbers DEFS 01240062 through 75.</p> <p>16 And I'd point your attention specifically</p> <p>17 to the middle e-mail on the first page from Diana E.</p> <p>18 Smith, and it cc's Dr. Philip Needleman and</p> <p>19 yourself, George S. Geis.</p> <p>20 A. Could you repeat the question?</p> <p>21 Q. Sure. Sure. Let me ask a different</p> <p>22 question, and -- and we'll -- we'll -- we're going</p> <p>23 to look at this document in just a second.</p> <p>24 A. Sure.</p>	<p style="text-align: center;">87</p> <p>1 here today is, you don't know, correct?</p> <p>2 A. What I'm -- what I'm saying is that the</p> <p>3 process, as I understood it, was that -- so I -- I</p> <p>4 have to put it in the context of what was going on</p> <p>5 at the time.</p> <p>6 Q. Go -- go ahead, sir.</p> <p>7 A. So there was Searle who had RAC. We then</p> <p>8 had a codevelopment, comarketing agreement with</p> <p>9 Pfizer.</p> <p>10 The process was, as described to me by</p> <p>11 Ms. Young and Kovitz, was that they were -- they</p> <p>12 were mirror images. They had representatives from</p> <p>13 the various disciplines on Pfizer and Searle for</p> <p>14 press releases and things that went public through</p> <p>15 the commercial side. That was in place, but we were</p> <p>16 right in the merger with Pharmacia. So things began</p> <p>17 to move.</p> <p>18 Both Ms. Young and Ms. Kovitz said, at</p> <p>19 the time, it wasn't actually precise anymore. That</p> <p>20 was their best recollection, because we were in the</p> <p>21 middle of the merger.</p> <p>22 So the -- the precise process and steps</p> <p>23 related to this particular press release, they could</p> <p>24 not say exactly how it went.</p>
<p style="text-align: center;">86</p> <p>1 Q. But you understand that you're testifying</p> <p>2 on behalf of Pharmacia regarding, quote, The</p> <p>3 issuance of the press release, including, but not</p> <p>4 limited to, the process for and individuals involved</p> <p>5 with drafting, editing and approving the press</p> <p>6 release, correct?</p> <p>7 A. Yes.</p> <p>8 Q. You're designated to testify on that</p> <p>9 topic for Pharmacia?</p> <p>10 A. I understand that, yes.</p> <p>11 Q. Okay. And my question is, before we get</p> <p>12 to this document, who at Pharmacia, starting with</p> <p>13 the most senior person, approved the issuance of</p> <p>14 this press release?</p> <p>15 A. That, I don't know. This specific press</p> <p>16 release, I don't know.</p> <p>17 Can I give you context about --</p> <p>18 Q. We'll get to that in a second.</p> <p>19 A. Okay.</p> <p>20 Q. But my question is, you understand that</p> <p>21 you were designated to testify on behalf of</p> <p>22 Pharmacia --</p> <p>23 A. Sure.</p> <p>24 Q. -- who approved this, and your testimony</p>	<p style="text-align: center;">88</p> <p>1 But in -- but having said that, in</p> <p>2 principle, there was -- there was -- there would</p> <p>3 have been an agreement between the Searle</p> <p>4 representatives and the Pfizer representatives and</p> <p>5 possibly Pharmacia involved.</p> <p>6 Q. Okay. So let's break that down.</p> <p>7 At Searle, the RAC, or regulatory affairs</p> <p>8 committee, approved the press release, correct?</p> <p>9 A. They would have, yes.</p> <p>10 Q. And --</p> <p>11 A. That would be a fair --</p> <p>12 Q. And you don't know everybody that was on</p> <p>13 the RAC?</p> <p>14 A. Correct, I don't.</p> <p>15 Q. Do you know -- other than the people who</p> <p>16 you named who were on the RAC, do you know whether</p> <p>17 any other senior Searle individuals approved the</p> <p>18 press release?</p> <p>19 A. No, I don't.</p> <p>20 Q. Okay. Do you know whether Dr. Needleman</p> <p>21 approved the press release?</p> <p>22 A. I don't know.</p> <p>23 Q. Do you know whether Mr. Dick De Schutter</p> <p>24 approved the press release?</p>



<p style="text-align: center;">89</p> <p>1 A. I don't know.</p> <p>2 Q. Okay. And what have you done to</p> <p>3 determine whether either De Schutter or Needleman or</p> <p>4 other Searle senior executives approved the press</p> <p>5 release?</p> <p>6 A. When I spoke with -- as I said, when I</p> <p>7 spoke with Ms. Young and Ms. Kovitz, I asked them</p> <p>8 who would have approved it. They did not remember</p> <p>9 specifically who.</p> <p>10 Q. Did you ask Mr. Needleman if he approved</p> <p>11 it?</p> <p>12 A. No, I did not.</p> <p>13 Q. Did you ask Mr. De Schutter if he</p> <p>14 approved it?</p> <p>15 A. I did not.</p> <p>16 Q. Did you ask any other senior -- who --</p> <p>17 people who were, at this time, senior Searle</p> <p>18 executives whether they approved it?</p> <p>19 A. No, I did not.</p> <p>20 Q. And why -- why didn't you do that, I</p> <p>21 guess?</p> <p>22 A. Well, I went to the people who were</p> <p>23 responsible for press releases based on my</p> <p>24 understanding of what went on at Searle. So Sally</p>	<p style="text-align: center;">91</p> <p>1 asked them questions. But they did not talk about a</p> <p>2 written process.</p> <p>3 Q. Okay. Did you talk to any lawyers about</p> <p>4 it, like people that might have been in the legal</p> <p>5 department at Pharmacia that may have dealt with the</p> <p>6 protocol for how authorization of press release</p> <p>7 occurred in this period?</p> <p>8 A. I did not speak with the legal department</p> <p>9 at Searle about this.</p> <p>10 Q. All right. Now, going to Pharmacia, now,</p> <p>11 separate from Searle -- and I -- I understand you</p> <p>12 agree with me -- and I can show you the document --</p> <p>13 that as of April 17th, Searle was part of Pharmacia</p> <p>14 because the merger closed on March 31st, 2000.</p> <p>15 Do you -- do you --</p> <p>16 A. Say that again.</p> <p>17 Q. Do you agree with that?</p> <p>18 A. Could you repeat that?</p> <p>19 Q. The merger closed on March 31st, 2000; is</p> <p>20 that correct? And I can show you a document if you</p> <p>21 don't know from your own knowledge.</p> <p>22 A. I don't know from my -- my own knowledge</p> <p>23 exactly the date the merger legally existed.</p> <p>24 Q. Okay. I want to show you what I'm</p>
<p style="text-align: center;">90</p> <p>1 Benjamin Young was the head of PR who would have</p> <p>2 knowledge of the whole RAC process.</p> <p>3 Q. Do you know whether there was --</p> <p>4 MR. HOFF: Wait, wait.</p> <p>5 MR. SAHAM: Oh, I'm sorry.</p> <p>6 MR. HOFF: Did you finish?</p> <p>7 BY MR. SAHAM:</p> <p>8 Q. I didn't mean to interrupt.</p> <p>9 A. So I went to the person who understood</p> <p>10 the process, in my mind, the best. And it was</p> <p>11 through her department that much of these activities</p> <p>12 took place. So I went to what I thought was the</p> <p>13 knowledgeable and responsible source.</p> <p>14 Q. Do you know whether there's a written</p> <p>15 protocol or was a written protocol at Searle that</p> <p>16 described the process by which a press release would</p> <p>17 be approved, of this type?</p> <p>18 A. I do not know if there was a -- a written</p> <p>19 process.</p> <p>20 Q. And as a -- as a 30(b)(6) deponent, you</p> <p>21 didn't attempt to determine -- or review documents</p> <p>22 to determine whether there's a written protocol?</p> <p>23 A. Like I said, I spoke with the head of PR</p> <p>24 and the knowledgeable people of the process and</p>	<p style="text-align: center;">92</p> <p>1 marking as Plaintiffs' Exhibit 253.</p> <p>2 (WHEREUPON, a certain document was</p> <p>3 marked Plaintiffs' Deposition</p> <p>4 Exhibit No. 253, for identification,</p> <p>5 as of 12/10/2010.)</p> <p>6 BY MR. SAHAM:</p> <p>7 Q. And Exhibit 253 is what's referred to as</p> <p>8 an 8-K, a form 8-K that was filed with the SEC. And</p> <p>9 the second page of the document at the top indicates</p> <p>10 that "On March 31st, 2000, MP Sub, Incorporated, a</p> <p>11 Delaware corporation ('Merger Sub') wholly owned by</p> <p>12 Pharmacia Corporation (formerly Monsanto Company), a</p> <p>13 Delaware corporation ('Registrant'), merged ('the</p> <p>14 Merger') with and into Pharmacia &amp; Upjohn, Inc., a</p> <p>15 Delaware corporation (Pharmacia &amp; Upjohn), pursuant</p> <p>16 to an Agreement and Plan of Merger, dated as of</p> <p>17 December 19, 1999, as amended ('the Merger</p> <p>18 Agreement')."</p> <p>19 And hopefully, you'll accept my</p> <p>20 representation that as per this filing with the SEC,</p> <p>21 that the merger was finalized on March 31st of 2000,</p> <p>22 for the purposes of my next set of questions?</p> <p>23 A. Could you repeat it real quick?</p> <p>24 Q. I'm just saying the merger -- I -- I know</p>



<p>93</p> <p>1 it's hard to remember dates.</p> <p>2 It occurred on March 31st, 2000, the two</p> <p>3 companies became one, Searle and Pharmacia?</p> <p>4 A. So based on this document, yes, I would</p> <p>5 agree that's what this document says.</p> <p>6 Q. Okay. So as of -- assuming that document</p> <p>7 is accurate -- and I know you're not a lawyer or</p> <p>8 work for the SEC, but assuming the merger closed on</p> <p>9 March 31st, when this press release was being</p> <p>10 reviewed between April 7th and then went out on</p> <p>11 April 17th, it was one -- Pharmacia and Searle were</p> <p>12 one company, correct?</p> <p>13 A. I just want to get the dates of where</p> <p>14 the -- what we're talking about.</p> <p>15 Q. Right. This document -- and we're going</p> <p>16 to look at other versions of the press release. The</p> <p>17 one you're looking at, Exhibit 86, is dated -- the</p> <p>18 draft is dated April 11, 2000 --</p> <p>19 A. Okay.</p> <p>20 Q. -- 11 days after --</p> <p>21 A. Okay.</p> <p>22 Q. -- the merger.</p> <p>23 A. I agree that April 11 is after</p> <p>24 March 31st.</p>	<p>95</p> <p>1 BY THE WITNESS:</p> <p>2 A. Could you please repeat it? I'm sorry, I</p> <p>3 just want to get this right.</p> <p>4 BY MR. SAHAM:</p> <p>5 Q. Yeah. Who at Pharmacia -- we've talked</p> <p>6 about the Searle RAC and --</p> <p>7 A. Right.</p> <p>8 Q. -- people like that.</p> <p>9 A. Right.</p> <p>10 Q. Other than those people who you named</p> <p>11 already, who -- as a 30(b)(6) witness or with your</p> <p>12 own knowledge, who at Pharmacia, senior executives,</p> <p>13 to your knowledge, approved that press release?</p> <p>14 A. I don't --</p> <p>15 MR. HOFF: Objection to form.</p> <p>16 BY THE WITNESS:</p> <p>17 A. I don't know.</p> <p>18 BY MR. SAHAM:</p> <p>19 Q. Okay. Do you know if Pharmacia had some</p> <p>20 sort of similar RAC entity that approved the press</p> <p>21 release?</p> <p>22 A. I don't know.</p> <p>23 Q. Okay. And what did you do to attempt to</p> <p>24 find that out?</p>
<p>94</p> <p>1 Q. Right. Okay. So for the purposes of</p> <p>2 these questions, I'm representing to you, if -- if</p> <p>3 that is accurate that the merger closed on</p> <p>4 March 31st -- which I know you're not an expert on</p> <p>5 that -- on April 11th, Pharmacia and Searle are one,</p> <p>6 correct?</p> <p>7 A. Legally speaking, I would agree.</p> <p>8 Q. Okay. So --</p> <p>9 MR. HOFF: It's actually Pharmacia &amp; Upjohn and</p> <p>10 Monsanto are one.</p> <p>11 MR. SAHAM: Great. Great.</p> <p>12 BY MR. SAHAM:</p> <p>13 Q. So now my next set of questions -- you</p> <p>14 know, I asked you about, you know, what you did to</p> <p>15 figure out who at Searle approved the press release.</p> <p>16 Who, starting with the most-senior people</p> <p>17 at Pharmacia, to your knowledge as the 30(b)(6)</p> <p>18 deponent, approved the press release at Pharmacia</p> <p>19 other than the Searle people who you referenced who</p> <p>20 were legally part of Pharmacia at this point? But</p> <p>21 I'm getting at people who were, you know, for -- for</p> <p>22 lack of a better word, they were -- they were at</p> <p>23 Pharmacia before the two companies joined.</p> <p>24 MR. HOFF: Objection to form.</p>	<p>96</p> <p>1 A. So with counsel, there was an outreach to</p> <p>2 a couple people who were a part of the Searle</p> <p>3 organization and the Pharmacia organization. There</p> <p>4 was a -- a woman named Diana Morales Smith who was</p> <p>5 in PR from Searle. There was an attempt made to</p> <p>6 reach out to her to ask her questions and she did</p> <p>7 not respond.</p> <p>8 There was a gentleman named Craig Tooman</p> <p>9 who is -- my understanding -- from Pharmacia, who</p> <p>10 was in PR. And I don't -- again, I don't know</p> <p>11 exactly if there was a RAC committee or whatever,</p> <p>12 but he -- his -- his -- he was involved in PR and in</p> <p>13 press releases.</p> <p>14 Through Dr. Ando, there was an outreach</p> <p>15 to Mr. Tooman to ask questions, and Mr. Tooman did</p> <p>16 not respond. So there was an outreach to a couple</p> <p>17 people who -- who, I think, were intimately</p> <p>18 involved. And I shouldn't say that, but I think,</p> <p>19 and they did not respond.</p> <p>20 Q. Would you agree with me -- and this is a</p> <p>21 very simple question -- that the company, Pharmacia,</p> <p>22 issued this press release? Is that an accurate</p> <p>23 statement?</p> <p>24 A. The company did issue this.</p>



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<p style="text-align: center;">97</p> <p>1 Q. And Pfizer jointly issued this?</p> <p>2 A. My understanding of the process is that,</p> <p>3 yes, Pharmacia -- excuse me. Repeat it.</p> <p>4 Are you talking about Pharmacia or</p> <p>5 Pfizer?</p> <p>6 Q. Two different questions.</p> <p>7 I think we just established Pharmacia</p> <p>8 issued the April 17th press release, correct?</p> <p>9 A. Right.</p> <p>10 Q. You would agree with me that's accurate?</p> <p>11 A. Yes.</p> <p>12 Q. And the next question, totally separate</p> <p>13 question, did Pfizer coissue the press release with</p> <p>14 Pharmacia?</p> <p>15 A. I don't know that.</p> <p>16 Q. Okay.</p> <p>17 A. I don't know. Because of the -- as -- as</p> <p>18 Ms. Young and Kovitz described, at that time, there</p> <p>19 was this period of change going on where they could</p> <p>20 not describe exactly what happened and who was at</p> <p>21 the table for this particular press release.</p> <p>22 Q. And you are not designated to testify</p> <p>23 here today on behalf of Pfizer regarding who issued</p> <p>24 the press release, correct?</p>	<p style="text-align: center;">99</p> <p>1 You're listed as the cc, George S. Geis on the first</p> <p>2 page.</p> <p>3 A. I see that. I just am trying to see if</p> <p>4 it makes it clear that the press release was</p> <p>5 attached to the e-mail, because I don't recognize</p> <p>6 the e-mail or the press release. But this e-mail</p> <p>7 was sent to me. I'm just trying to see if it says</p> <p>8 the press release is attached.</p> <p>9 Q. Well, it say, "Thank you for the</p> <p>10 considerable amount of time you spent this morning</p> <p>11 reviewing the draft CLASS media materials."</p> <p>12 A. Well, that's --</p> <p>13 Q. "We made a lot of headway and we were</p> <p>14 able to refine the materials even further this</p> <p>15 afternoon in a Searle-only RAC session."</p> <p>16 Then there's three documents attached in</p> <p>17 Word, the first of which is the Fact Sheet,</p> <p>18 Celecoxib Long-Term Arthritis Safety Study, which</p> <p>19 bears a consecutive Bates number to the e-mail, and</p> <p>20 that is four pages.</p> <p>21 And then starting at the fifth page,</p> <p>22 which is last three Bates number 067, there's a</p> <p>23 Draft 4/11/00 of the April 17th, 2000 press release,</p> <p>24 and that is -- one, two, three -- four pages long.</p>
<p style="text-align: center;">98</p> <p>1 A. Not that I know of.</p> <p>2 Q. Okay. Somebody else is going to be</p> <p>3 presumably -- well, you don't know that --</p> <p>4 A. I don't know.</p> <p>5 Q. -- but you're -- you're not designated</p> <p>6 for that point?</p> <p>7 A. I don't believe so. It's my</p> <p>8 understanding --</p> <p>9 Q. Just Pharmacia?</p> <p>10 A. -- as a designee.</p> <p>11 That is my understanding.</p> <p>12 Q. Now, looking back -- well, before we look</p> <p>13 back at 86, you -- so you don't know who at Pfizer</p> <p>14 approved the press release?</p> <p>15 A. I do not.</p> <p>16 Q. Okay.</p> <p>17 MR. HOFF: Objection to form.</p> <p>18 BY MR. SAHAM:</p> <p>19 Q. And looking back at Exhibit 86, you would</p> <p>20 agree with me that you received the press release in</p> <p>21 the form attached as part of 86 on or about</p> <p>22 April 11, 2000, six days before it was issued,</p> <p>23 correct?</p> <p>24 And I'd refer you to the middle e-mail.</p>	<p style="text-align: center;">100</p> <p>1 And then there's another attachment of</p> <p>2 the -- entitled Fact Sheet after that, which would</p> <p>3 correspond with the three word icons on the first</p> <p>4 page of the e-mail, correct?</p> <p>5 MR. HOFF: Is there a question somewhere?</p> <p>6 BY MR. SAHAM:</p> <p>7 Q. Well, is it correct that there's three</p> <p>8 icons there that are labeled Facts, rac R-e-L,</p> <p>9 presumably RAC release, and Factsheet 4-11, that</p> <p>10 those three icons would appear to correspond with</p> <p>11 the three attachments to the e-mail, correct, sir?</p> <p>12 MR. HOFF: Objection to form.</p> <p>13 BY THE WITNESS:</p> <p>14 A. I'm just trying to look at this closely</p> <p>15 to make sure that the icon does actually match</p> <p>16 the -- the press release you're referring to.</p> <p>17 BY MR. SAHAM:</p> <p>18 Q. Right. Like, I'm looking at the middle</p> <p>19 icon.</p> <p>20 A. Yep.</p> <p>21 Q. It says CLASSracrel, which would be</p> <p>22 release in my --</p> <p>23 A. Yes. And at the top of the press</p> <p>24 release, the top left-hand corner, it says</p>



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<p>101</p> <p>1 CLASSracrel.</p> <p>2 Q. So you would agree with me that you</p> <p>3 received this draft electronically on or about</p> <p>4 April 11, 2000?</p> <p>5 A. I don't recall having received it, but</p> <p>6 the e-mail says I was copied.</p> <p>7 Q. And it would have been e-mailed to you in</p> <p>8 the ordinary scope of business at corporation</p> <p>9 Pharmacia, correct?</p> <p>10 A. I don't remember it either way, but it</p> <p>11 appears it was sent to me.</p> <p>12 Q. But it wasn't sent to you in some</p> <p>13 personal capacity? You were working for Pharmacia</p> <p>14 at the time and so were these other individuals?</p> <p>15 A. I was. I can't --</p> <p>16 Q. Okay.</p> <p>17 A. -- you know --</p> <p>18 Q. Diana Smith --</p> <p>19 A. -- I can't answer for anybody else.</p> <p>20 Q. Do you know who Diana Smith was who sent</p> <p>21 that e-mail?</p> <p>22 A. Diana Smith is the woman I referred to</p> <p>23 earlier. Diana -- I believe it was Morales Smith,</p> <p>24 and at the -- as I remember her, she was an employee</p>	<p>103</p> <p>1 but I'm not sure whether -- because at the time,</p> <p>2 again, we have Pfizer and now new people from</p> <p>3 Pharmacia. I can't recall --</p> <p>4 Q. And here, next to --</p> <p>5 A. -- which organization.</p> <p>6 Q. I'm sorry, next to his name, it says</p> <p>7 Non-Monsanto/Off-Site.</p> <p>8 So he didn't work for Searle, right?</p> <p>9 A. The -- correct. I understand that. I</p> <p>10 just --</p> <p>11 Q. You just can't remember whether he worked</p> <p>12 for Pfizer or -- or Pharmacia?</p> <p>13 A. Correct.</p> <p>14 Q. And I represent to you he worked for --</p> <p>15 not that that's worth anything, but he did work for</p> <p>16 Pfizer at the time.</p> <p>17 A. Okay.</p> <p>18 Q. Do you know who Irene Condon is?</p> <p>19 A. I do not.</p> <p>20 Q. Celeste Torello?</p> <p>21 A. I do not know who that is.</p> <p>22 Q. Phyllis Christesen?</p> <p>23 A. I remember Phyllis Christesen as an</p> <p>24 employee of Pfizer.</p>
<p>102</p> <p>1 of -- of Searle in the PR department.</p> <p>2 Q. And there are several people that it's</p> <p>3 addressed to in the To line, the e-mail there,</p> <p>4 Catherine Wertjes, W-e-r-t-j-e-s, who you referred</p> <p>5 to earlier?</p> <p>6 A. Yes, that's correct.</p> <p>7 Q. Jerome --</p> <p>8 A. Her name is here.</p> <p>9 Q. Jerome Prah, P-r-a-h-l, Al Bello, John</p> <p>10 G. Fort, Rich Montwill, Deborah D. Armstrong, Alicia</p> <p>11 Byer, do those people appear to be the Searle RAC</p> <p>12 committee?</p> <p>13 A. I can't state that for certain.</p> <p>14 Q. But some --</p> <p>15 A. I don't know. I'm saying I don't know.</p> <p>16 Q. But some of those people were on the RAC?</p> <p>17 A. Yes. As I was told, yes.</p> <p>18 Q. And then do you know who Guy Buckland</p> <p>19 was?</p> <p>20 A. My remembrance of Guy Buckland --</p> <p>21 Q. Was he a Pfizer employee?</p> <p>22 A. I can't recall.</p> <p>23 Q. You just don't remember?</p> <p>24 A. I can't recall. I remember Guy Buckland,</p>	<p>104</p> <p>1 Q. Okay. So at least one Pfizer employee</p> <p>2 you remember received this, correct, or was --</p> <p>3 A. Well, I -- I remember Phyllis Christesen</p> <p>4 from Pfizer.</p> <p>5 Q. And she was -- and -- and she was sent</p> <p>6 this e-mail, correct, sir?</p> <p>7 A. Well, she was copied on this e-mail.</p> <p>8 Q. Right, as a To?</p> <p>9 A. As a To.</p> <p>10 Q. And then Beth Levine, do you know who</p> <p>11 that is?</p> <p>12 A. I do not.</p> <p>13 Q. Heidi Chen?</p> <p>14 A. Are you asking me, do I know who she is?</p> <p>15 Q. Yeah, do you know who she is?</p> <p>16 A. I do not.</p> <p>17 Q. Leslie Tive?</p> <p>18 A. Again, are you asking me, do I know her</p> <p>19 or if the name --</p> <p>20 Q. Yes, do you know who that person is?</p> <p>21 A. I do not know her.</p> <p>22 Q. And Will Kane, do you know who that is?</p> <p>23 A. I do not.</p> <p>24 Q. Did you attempt to figure out who any of</p>



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<p style="text-align: center;">105</p> <p>1 these people were as part of your 30(b)(6)</p> <p>2 preparations?</p> <p>3 A. No. I did not reach out to these people</p> <p>4 and had no reason to because I don't know them.</p> <p>5 Q. Right. No, but I'm saying, did you</p> <p>6 attempt to figure out who they were so you could</p> <p>7 testify on behalf of Pharmacia about who approved</p> <p>8 the press release?</p> <p>9 A. I don't recall having seen this list of</p> <p>10 people.</p> <p>11 Q. And I'm just asking you what --</p> <p>12 A. Yeah, I don't recall having seen this</p> <p>13 list of people, so I wouldn't have even made the</p> <p>14 connection.</p> <p>15 Q. And then the first cc listed here as</p> <p>16 having received this e-mail is Dr. Needleman,</p> <p>17 correct?</p> <p>18 A. His name is on the cc list, yes.</p> <p>19 Q. Okay. So presumably it was sent to him,</p> <p>20 as well, correct?</p> <p>21 A. I don't know either way. His name</p> <p>22 appears as the cc --</p> <p>23 Q. Okay.</p> <p>24 A. -- on the cc list.</p>	<p style="text-align: center;">107</p> <p>1 Papa and others.</p> <p>2 And the subject line says RAC-Approved</p> <p>3 CLASS Press Materials. And it goes on to state,</p> <p>4 Attached are the final RAC-approved CLASS press</p> <p>5 materials. Pending any other final Pharmacia</p> <p>6 sign-offs, these materials will be distributed to</p> <p>7 the media on Monday morning followed by a news</p> <p>8 teleconference with Drs. Geis, Silverstein, Simon</p> <p>9 and Whelton at 10:30 a.m. Eastern time.</p> <p>10 Now, this document indicates, as you just</p> <p>11 testified earlier, that the press release was</p> <p>12 proved -- approved by the RAC, correct?</p> <p>13 A. That's what this says.</p> <p>14 Q. And then it also refers to pending any</p> <p>15 final Pharmacia sign-offs.</p> <p>16 What did you do to determine what final</p> <p>17 Pharmacia sign-offs occurred with respect to the</p> <p>18 April 17th press release?</p> <p>19 A. As I stated earlier, I reached out to</p> <p>20 Ms. Kovitz and Ms. Young to de- -- to describe the</p> <p>21 general process of approvals at Searle and at the</p> <p>22 time -- at this time of the merger and with the</p> <p>23 presence of Pfizer.</p> <p>24 We talked specifically about the press</p>
<p style="text-align: center;">106</p> <p>1 Q. And Dr. Friedman is cc'd, as well?</p> <p>2 A. Dr. Friedman's name is on the cc list.</p> <p>3 Q. Okay. I want to show you what I'm</p> <p>4 marking as Plaintiffs' Exhibit 254.</p> <p>5 (WHEREUPON, a certain document was</p> <p>6 marked Plaintiffs' Deposition</p> <p>7 Exhibit No. 254, for identification,</p> <p>8 as of 12/10/2010.)</p> <p>9 BY MR. SAHAM:</p> <p>10 Q. Could you please take a look at</p> <p>11 Plaintiffs' Exhibit 254.</p> <p>12 MR. SAHAM: And for the record, Plaintiffs'</p> <p>13 Exhibit 254 is, again, a one-page e-mail chain dated</p> <p>14 April 4 -- April 13th and April 14th, 2000, and it</p> <p>15 attaches drafts of the same three documents we were</p> <p>16 referring to in the April 11th draft -- or the</p> <p>17 April 11th exhibit which I'd marked as Exhibit 86.</p> <p>18 And this document bears Bates numbers DEFS 03835807</p> <p>19 through 5816.</p> <p>20 And it -- and the e-mail -- I'm looking</p> <p>21 at the e-mail from Diana E. Smith down at the bottom</p> <p>22 of the first page, and it's dated April 13th, 2000,</p> <p>23 to Philip Needleman and Richard U. De Schutter, D-e,</p> <p>24 space, S-c-h-u-t-t-e-r, and also Alan Heller, Joseph</p>	<p style="text-align: center;">108</p> <p>1 release around this time. There was outreach to</p> <p>2 Ms. Smith and Mr. Tooman, who did not respond. So</p> <p>3 that's what I did to get an understanding of this.</p> <p>4 Q. And this document indi- -- indicates it</p> <p>5 was sent, the press re- -- the draft of the press</p> <p>6 release, after it was approved by RAC, was sent to</p> <p>7 Dr. Needleman and Mr. De Schutter and Mr. Heller,</p> <p>8 correct?</p> <p>9 A. This does say that it's the final</p> <p>10 RAC-approved CLASS press materials.</p> <p>11 Q. And it was also sent to Paul G. Tooman,</p> <p>12 or Tooman, T-o-o-m-a-n -- or, I'm sorry, Craig</p> <p>13 Tooman, T-o-o-m-a-n, which is an individual referred</p> <p>14 to earlier.</p> <p>15 A. I'm sorry, I don't see --</p> <p>16 Q. If you drop down a few lines, it says</p> <p>17 Tooman, Craig?</p> <p>18 A. Yes, it does.</p> <p>19 Q. But you did not -- and I just want to</p> <p>20 confirm this, you didn't talk to Dr. Needleman,</p> <p>21 Mr. De Schutter or Mr. Heller to ask them whether</p> <p>22 they approved the issuance of this press release?</p> <p>23 A. No, I did not.</p> <p>24 Q. And could you describe what the purpose</p>



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<p style="text-align: center;">109</p> <p>1 of the RAC is?</p> <p>2 A. My understanding is that is -- my</p> <p>3 understanding of the RAC at Searle was to look at</p> <p>4 materials related to commercial -- commercial that</p> <p>5 were going to the public, including press releases,</p> <p>6 and that they were acceptable from a variety of</p> <p>7 perspectives, such as legal, regulatory, et cetera.</p> <p>8 And that then they would approve it, and then the</p> <p>9 people in the organization could use them -- those</p> <p>10 materials.</p> <p>11 Q. Okay. I want to show you what has been</p> <p>12 previously marked as Plaintiffs' Exhibit 240.</p> <p>13 Could you please take a look at</p> <p>14 Plaintiffs' Exhibit 240.</p> <p>15 MR. SAHAM: And for the record, Plaintiffs'</p> <p>16 Exhibit 240 is a one-page e-mail chain from Diana E.</p> <p>17 Smith that cc's Dr. Needleman, Dr. Friedman and</p> <p>18 yourself. It's dated April 7, 2000, and the entire</p> <p>19 document, it attaches, again, the same three, the</p> <p>20 two fact sheets and the press release, but this</p> <p>21 version is dated April 7, 2000, and it bears the</p> <p>22 Bates numbers DEFS 00589404 through 412.</p> <p>23 BY MR. SAHAM:</p> <p>24 Q. And I'd ask you, do you agree that you</p>	<p style="text-align: center;">111</p> <p>1 A. This says he was copied, yes.</p> <p>2 Q. And the same with Dr. Friedman and</p> <p>3 Mr. Papa?</p> <p>4 A. This says that Dr. Friedman and Mr. Papa</p> <p>5 were copied.</p> <p>6 Q. And Mr. Heller, as well?</p> <p>7 A. That's what -- it does say that</p> <p>8 Mr. Heller was cc'd on this.</p> <p>9 Q. I want to show you what I'm marking as</p> <p>10 Plaintiffs' Exhibit 255.</p> <p>11 (WHEREUPON, a certain document was</p> <p>12 marked Plaintiffs' Deposition</p> <p>13 Exhibit No. 255, for identification,</p> <p>14 as of 12/10/2010.)</p> <p>15 BY MR. SAHAM:</p> <p>16 Q. And I'd ask you if you recognize that</p> <p>17 press release? This -- this is a different press</p> <p>18 release. This is the May 23, 2000 San Diego</p> <p>19 Digestive Disease Week press release. It's entitled</p> <p>20 Findings From Celebrex Safety Study Show Traditional</p> <p>21 NSAID Comparators Can Cause Serious GI Complications</p> <p>22 Within First Days of Treatment.</p> <p>23 And I -- and I just ask you if you</p> <p>24 recognize that?</p>
<p style="text-align: center;">110</p> <p>1 would have -- that this e-mail would have been sent</p> <p>2 to you with these attachments as a cc on or about</p> <p>3 April 7, 2000?</p> <p>4 A. I see what's said here. The problem I</p> <p>5 have is, the icon at the bottom that references an</p> <p>6 S RAC rel.doc. Then you find what appears to be a</p> <p>7 press release, does not have the same notation. So</p> <p>8 I do not know if this is the press release that --</p> <p>9 that's being referred to in the icon.</p> <p>10 Q. But you don't --</p> <p>11 A. I -- I see a press release, yes, I see</p> <p>12 it. And I see an icon that says something about a</p> <p>13 press release, but I'm not sure I would say they're</p> <p>14 accurately connected.</p> <p>15 Q. But you don't dispute that you were sent</p> <p>16 at least some version of the April 17th press</p> <p>17 release via e-mail on or about April 7, 2000?</p> <p>18 A. In the text, it says, specifically, you</p> <p>19 will find the draft press release.</p> <p>20 So based on that, I would agree that</p> <p>21 the -- a press release was attached to the e-mail I</p> <p>22 was cc'd on.</p> <p>23 Q. And you also agree that it was sent to</p> <p>24 Dr. Needleman, a press release, as well?</p>	<p style="text-align: center;">112</p> <p>1 A. I -- I recently saw this, yes.</p> <p>2 Q. Okay. And it --</p> <p>3 A. But recently.</p> <p>4 Q. Does it appear to be a press release that</p> <p>5 was issued regarding CLASS in conjunction with the</p> <p>6 disease -- Digestive Disease Week in San Diego about</p> <p>7 a month after the April 17th press release?</p> <p>8 A. It says -- in the first paragraph, it</p> <p>9 refers to data presented during Digestive Disease</p> <p>10 Week, so it appears that this is referencing what</p> <p>11 was presented there.</p> <p>12 Q. Okay. Can you turn back to Exhibit 254,</p> <p>13 which is the April 14th RAC-approved press release.</p> <p>14 And at the bottom -- I read this earlier</p> <p>15 but I wanted to ask you a few questions about it --</p> <p>16 it says -- and I'm just going to read it again, just</p> <p>17 to refer you back to it.</p> <p>18 It says, "Pending any other final</p> <p>19 Pharmacia sign-offs, these materials will be</p> <p>20 distributed to the media on Monday morning, followed</p> <p>21 by a news" con- -- "teleconference with Drs. Geis,</p> <p>22 Silverstein, Simon and Whelton at 10:30 a.m."</p> <p>23 Does that refresh your recollection that</p> <p>24 you may have participated in a call with the media</p>



<p style="text-align: center;">113</p> <p>1 on or about April 17, 2000, regarding the CLASS</p> <p>2 results?</p> <p>3 A. No, it doesn't.</p> <p>4 Q. But you don't dispute that you did?</p> <p>5 A. I don't recall it.</p> <p>6 Q. Okay. You just don't remember one way or</p> <p>7 the other?</p> <p>8 A. I don't remember one way or another --</p> <p>9 Q. You remember talking about CLASS</p> <p>10 publicly, but you just don't remember the dates that</p> <p>11 you did so?</p> <p>12 MR. HOFF: Objection to form.</p> <p>13 BY THE WITNESS:</p> <p>14 A. You have to be more specific as to, do I</p> <p>15 remember -- do I remember talking publicly about</p> <p>16 CLASS -- when? When are you speaking of?</p> <p>17 BY MR. SAHAM:</p> <p>18 Q. I'm saying, you remember, generally,</p> <p>19 doing it, you just don't remember the dates? You</p> <p>20 remember, at some point, at least, you talked to</p> <p>21 reporters about CLASS, you just don't know whether</p> <p>22 you did it on April 17th or not?</p> <p>23 MR. HOFF: Objection to form.</p> <p>24 BY THE WITNESS:</p>	<p style="text-align: center;">115</p> <p>1 A. It doesn't say that, specifically.</p> <p>2 Q. Well, you were designated as the</p> <p>3 representative --</p> <p>4 A. Right.</p> <p>5 Q. -- of Pharmacia --</p> <p>6 A. Right.</p> <p>7 Q. -- regarding the April 17 press release.</p> <p>8 So presumably, you can identify whether or not --</p> <p>9 A. Yeah.</p> <p>10 Q. -- this is it.</p> <p>11 A. This looks like it is like the press</p> <p>12 release I understand had been released. But, you</p> <p>13 know, as you saw before, there were drafts of it,</p> <p>14 and I don't see anything here that says it's stamped</p> <p>15 final or anything like that.</p> <p>16 So I'm saying, it looks like it is, but I</p> <p>17 can't guarantee --</p> <p>18 Q. Did you review --</p> <p>19 A. -- to you that I know that this thing you</p> <p>20 handed me was the final that was released that day.</p> <p>21 Q. Well --</p> <p>22 A. That's all I'm saying.</p> <p>23 Q. -- in your preparations as the, you know,</p> <p>24 corporate representative of Pharmacia --</p>
<p style="text-align: center;">114</p> <p>1 A. I talked -- I spoke to reporters at some</p> <p>2 point about CLASS. I don't recall doing so this</p> <p>3 early after we had the results from CLASS.</p> <p>4 BY MR. SAHAM:</p> <p>5 Q. You just don't remember doing it?</p> <p>6 A. I don't -- I don't remember doing it --</p> <p>7 Q. Okay.</p> <p>8 A. -- correct.</p> <p>9 Q. Now, I want to show you what's been</p> <p>10 marked previously as Exhibit 67. And this is just</p> <p>11 -- this is the actual press release that was issued</p> <p>12 on -- well, I -- I strike that.</p> <p>13 I'm just showing you what's been marked</p> <p>14 as Plaintiffs' Exhibit 67, and I'd ask you, first,</p> <p>15 if you recognize what that is?</p> <p>16 What is this document, Exhibit 67, sir?</p> <p>17 A. It is a document that's -- is -- is</p> <p>18 describing the -- the presentation and elements of</p> <p>19 the presentation that Dr. Silverstein gave at the</p> <p>20 American College of Physicians --</p> <p>21 Q. And --</p> <p>22 A. -- sometime around April 17th.</p> <p>23 Q. Okay. And this is a press release that</p> <p>24 was issued by Pharmacia on or about April 17, 2000?</p>	<p style="text-align: center;">116</p> <p>1 MR. HOFF: Can I save some time --</p> <p>2 BY MR. SAHAM:</p> <p>3 Q. -- to testify --</p> <p>4 MR. HOFF: -- and stipulate that this is the</p> <p>5 press release?</p> <p>6 MR. SAHAM: Yeah. Do you stipulate, then?</p> <p>7 MR. HOFF: This is -- this was -- this was the</p> <p>8 press release that was issued on April 17th.</p> <p>9 MR. SAHAM: Okay. So stipulated.</p> <p>10 MR. HOFF: Fine.</p> <p>11 THE WITNESS: Okay.</p> <p>12 MR. HOFF: So you can now ask --</p> <p>13 MR. SAHAM: Okay.</p> <p>14 MR. HOFF: -- your real questions.</p> <p>15 MR. SAHAM: Now we can all go home, John.</p> <p>16 MR. HOFF: Well, I'm okay with that.</p> <p>17 BY MR. SAHAM:</p> <p>18 Q. Okay. So this -- we've agreed now that</p> <p>19 this was the press release that was issued on</p> <p>20 April 17th --</p> <p>21 A. Okay.</p> <p>22 Q. -- that's been marked as Exhibit 67.</p> <p>23 A. Okay.</p> <p>24 Q. And I want to turn your attention</p>



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<p>117</p> <p>1 specifically to the second page of the document, the</p> <p>2 third paragraph, the first sentence, and I'll read</p> <p>3 it into the record.</p> <p>4 It states, "The study, funded by Searle</p> <p>5 and Pfizer, Inc., found that Celebrex patients</p> <p>6 experienced significantly fewer symptomatic GI</p> <p>7 ulcers and ulcer complications compared with</p> <p>8 Ibuprofen or Diclofenac."</p> <p>9 That statement is not accurate with</p> <p>10 respect to Diclofenac, correct?</p> <p>11 MR. HOFF: Objection to form.</p> <p>12 BY THE WITNESS:</p> <p>13 A. I read this -- I read this sentence to</p> <p>14 indicate that Celebrex was not different than</p> <p>15 Ibupro- -- than the analysis of Ibuprofen and</p> <p>16 Diclofenac together.</p> <p>17 BY MR. SAHAM:</p> <p>18 Q. You -- you read the word "were" to mean</p> <p>19 Ibuprofen and Diclofenac together? And I'm</p> <p>20 specifically referring to the sentence I just read.</p> <p>21 A. Yeah, I -- I -- I see what you are</p> <p>22 saying. I am reading the sentence and the context</p> <p>23 of the -- of the whole document, and I read it as</p> <p>24 the -- this is Ibuprofen with Diclofenac as a</p>	<p>119</p> <p>1 Silverstein presented. And -- and, again, if I</p> <p>2 could hearken back to what I was told by Ms. --</p> <p>3 Ms. Young and Ms. Kovitz, in the press release, you</p> <p>4 can only -- by FDA rules or laws, you can only</p> <p>5 present results that have been presented publicly.</p> <p>6 And the data that was presented publicly</p> <p>7 for ulcer complications and the combination of</p> <p>8 symptomatic ulcers in ulcer complications by</p> <p>9 Dr. Silverstein was the Ibuprofen plus the</p> <p>10 Diclofenac.</p> <p>11 So that's -- that is the basis of this</p> <p>12 whole -- the data that is presented --</p> <p>13 BY MR. SAHAM:</p> <p>14 Q. Fair --</p> <p>15 A. -- here.</p> <p>16 Q. Fair enough.</p> <p>17 My question, then, we -- we presented to</p> <p>18 you earlier, which is marked as -- you know, the</p> <p>19 slides, which we marked as 252, the slides that were</p> <p>20 presented at ACP, so you could put those in front of</p> <p>21 you, as well.</p> <p>22 You're saying that the -- the press</p> <p>23 release goes along with what was presented at ACP?</p> <p>24 A. My understand- -- my understanding is the</p>
<p>118</p> <p>1 combined group.</p> <p>2 Q. So you read the "or" to mean and,</p> <p>3 correct?</p> <p>4 A. I read it to mean that this -- these two</p> <p>5 were together in -- in the analysis.</p> <p>6 Q. Okay. This -- this document, though,</p> <p>7 Exhibit 67, which has been marked as Exhibit 67,</p> <p>8 does not disclose to the reader that there was no</p> <p>9 statistically significant comparison between</p> <p>10 Celebrex and Diclofenac for symptomatic GI ulcers</p> <p>11 and ulcer complications together; is that correct,</p> <p>12 sir?</p> <p>13 A. Could you repeat it? I'm sorry.</p> <p>14 Q. My question is, this document,</p> <p>15 Exhibit 67, the press release --</p> <p>16 A. Yes.</p> <p>17 Q. -- does not disclose to the reader that</p> <p>18 there was no statistically significant comparison in</p> <p>19 CLASS with respect to the combined endpoint of</p> <p>20 symptomatic GI ulcers and complicated ulcers</p> <p>21 together that were statistically significant?</p> <p>22 MR. WEISS: Object to the form.</p> <p>23 BY THE WITNESS:</p> <p>24 A. This document describes what Fred</p>	<p>120</p> <p>1 press release by FDA rules can only present data</p> <p>2 that was presented in the public.</p> <p>3 Q. Okay. And my question to you, given</p> <p>4 that, whether you want to look at Exhibit 252 and</p> <p>5 Exhibit 67 together or just Exhibit 67, the press</p> <p>6 release, the reader of that press release would not</p> <p>7 be made aware that there was no statistically</p> <p>8 significant comparison between Celebrex and</p> <p>9 Diclofenac as part of the CLASS study with respect</p> <p>10 to symptomatic GI ulcers and ulcer complications</p> <p>11 together; is that correct, sir?</p> <p>12 A. The read- -- reader is made aware of what</p> <p>13 was presented by Dr. Silverstein. These slides,</p> <p>14 you're saying, are the slides that Dr. Silverstein</p> <p>15 presented, and this press release is consistent with</p> <p>16 that, that it is the combined Ibuprofen and</p> <p>17 Diclofenac analysis together, what is -- that is</p> <p>18 described here.</p> <p>19 Q. I understand that, sir. But my question</p> <p>20 to you is a very specific question.</p> <p>21 MR. HOFF: Did you finish your answer?</p> <p>22 BY THE WITNESS:</p> <p>23 A. And that -- and -- and by law, that's all</p> <p>24 they can present.</p>



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<p>121</p> <p>1 BY MR. SAHAM:</p> <p>2 Q. That -- well enough that maybe -- you may</p> <p>3 be a lawyer, you may not, I don't know.</p> <p>4 A. Right.</p> <p>5 Q. You may be an expert on it.</p> <p>6 My question to you -- let's look at</p> <p>7 Exhibit 67, the press release that was issued on the</p> <p>8 wire services on April 17, 2000, if somebody read</p> <p>9 this press release, sir, they would not be made</p> <p>10 aware that as part of the CLASS trial, there was not</p> <p>11 a statistically significant comparison between</p> <p>12 Celebrex and Diclofenac with respect to the endpoint</p> <p>13 of symptomatic GI ulcers and ulcer complications; is</p> <p>14 that correct, sir?</p> <p>15 A. They would not be aware of analyses that</p> <p>16 were done outside of what Dr. Silverstein presented.</p> <p>17 So there's a lot of analyses outside of what</p> <p>18 Dr. Silverstein presented that were not put in here.</p> <p>19 I would agree that -- that comparison to Diclofenac</p> <p>20 is not in here.</p> <p>21 Q. Okay. So if you read this, you wouldn't</p> <p>22 know that there wasn't a statistically significant</p> <p>23 comparison between Celebrex and Diclofenac at the</p> <p>24 symptomatic GI ulcers combined with ulcer</p>	<p>123</p> <p>1 is talking about the combined endpoint, symptomatic</p> <p>2 GI ulcers and ulcer complications, correct? That's</p> <p>3 the combined endpoint of those two endpoints</p> <p>4 together?</p> <p>5 A. I want to make sure we're looking --</p> <p>6 reading the same line. So I'm on what appears to be</p> <p>7 page 2, Paragraph 3.</p> <p>8 Q. The first sentence.</p> <p>9 A. The study funded experienced</p> <p>10 significantly fewer symptomatic -- symptomatic GI</p> <p>11 ulcers and ulcer complications.</p> <p>12 That combined endpoint, yes, I agree this</p> <p>13 sentence is referring to that.</p> <p>14 I also will submit that they are saying</p> <p>15 the -- the comparison is Celebrex with -- compared</p> <p>16 to the combined Ibuprofen and Diclofenac.</p> <p>17 Q. Okay. And -- and that's because you're</p> <p>18 interpreting the "or" to mean the two together?</p> <p>19 A. I'm interpreting, yes, in the context of</p> <p>20 what the first -- this whole document in the</p> <p>21 first -- in the first paragraph, it talks about that</p> <p>22 it was a combined --</p> <p>23 Q. You -- you'd agree with me that a</p> <p>24 reasonable person could disagree with you and read</p>
<p>122</p> <p>1 complications endpoint, correct?</p> <p>2 A. If -- your question is, if I read this?</p> <p>3 Q. Well, let me read -- I'll ask a better</p> <p>4 question.</p> <p>5 If by reading this press release, the</p> <p>6 reader of the press release would not be made aware,</p> <p>7 by reading this press release, that there was no</p> <p>8 statistically significant comparison between</p> <p>9 Celebrex and Diclofenac at the endpoint of GI --</p> <p>10 symptomatic GI ulcers and ulcer complications</p> <p>11 combined, correct -- is that correct, sir?</p> <p>12 A. So in and of itself, by itself in this</p> <p>13 press release, they do not talk about that analysis.</p> <p>14 Q. Okay. And they also -- this press</p> <p>15 release also doesn't reveal that there's no</p> <p>16 statistically significant comparison between</p> <p>17 Celebrex and Diclofenac on the ulcer complication</p> <p>18 endpoint, correct?</p> <p>19 A. Could you repeat it? Because I think you</p> <p>20 said it in a way that --</p> <p>21 Q. Right. My --</p> <p>22 A. -- it's not correct.</p> <p>23 Q. -- my first question, which I think we</p> <p>24 established, the sentence here that we started with</p>	<p>124</p> <p>1 the "or" in its ordinary usage, as meaning Ibuprofen</p> <p>2 or Diclofenac?</p> <p>3 MR. HOFF: Objection to form.</p> <p>4 BY MR. SAHAM:</p> <p>5 Q. Would you agree that that's possible,</p> <p>6 sir?</p> <p>7 MR. HOFF: Objection to form.</p> <p>8 BY THE WITNESS:</p> <p>9 A. Anything's possible, but I wouldn't agree</p> <p>10 with that.</p> <p>11 BY MR. SAHAM:</p> <p>12 Q. Okay. Now -- now, we're getting back to</p> <p>13 my set of questions about what's not in Exhibit 67.</p> <p>14 And my first question -- and I think you've agreed</p> <p>15 to this, that this combined endpoint that's being</p> <p>16 referred to in the sentence we've been reading,</p> <p>17 that -- and -- and -- and now I'm going to ask --</p> <p>18 ask my question -- well -- well, strike that.</p> <p>19 I'm going to ask a different question. I</p> <p>20 think I've already asked this and I think you've</p> <p>21 already answered it, but I just want to make sure.</p> <p>22 The reader of this press release would</p> <p>23 not know by just reading this press release that</p> <p>24 there was no statistically significant difference on</p>



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<p>125</p> <p>1 this combined endpoint between Celebrex and</p> <p>2 Diclofenac alone; is that correct, sir?</p> <p>3 MR. HOFF: Objection to form.</p> <p>4 BY THE WITNESS:</p> <p>5 A. That analysis, comparing Celebrex for the</p> <p>6 combined endpoint of symptomatic ulcers and ulcer</p> <p>7 complications versus Diclofenac is not referenced</p> <p>8 here.</p> <p>9 BY MR. SAHAM:</p> <p>10 Q. Okay. And -- and if it was, it would</p> <p>11 have to say that there was no statistically</p> <p>12 significant difference on that comparison, correct,</p> <p>13 sir?</p> <p>14 A. I don't know what you mean by "have to</p> <p>15 say."</p> <p>16 Q. It's accurate that there was no</p> <p>17 statistically significant difference on this</p> <p>18 combined endpoint at either six months or for the</p> <p>19 entire study when Celebrex was compared to</p> <p>20 Diclofenac?</p> <p>21 A. For reference, you'll have to give me the</p> <p>22 final data, because I don't have it --</p> <p>23 Q. I'd be --</p> <p>24 A. -- memorized.</p>	<p>127</p> <p>1 final study report?</p> <p>2 A. It appears to be, have -- not having gone</p> <p>3 through it page by page.</p> <p>4 Q. And it is -- if you turn to the second</p> <p>5 page, it's signed by James Lefkowitz and William W.</p> <p>6 Zhao?</p> <p>7 A. Yes, this document is.</p> <p>8 Q. And -- and what's the final study report?</p> <p>9 A. Within -- within the pharmaceutical</p> <p>10 industry, when a clinical trial is completed, the</p> <p>11 database is locked, secured analyses are run, and</p> <p>12 the analyses and all the data, what are considered</p> <p>13 the final data, are put into a document called the</p> <p>14 final study report.</p> <p>15 The report describes the intent of the</p> <p>16 study, the -- a summary of the protocol, a summary</p> <p>17 of the analysis plan. The -- the results are</p> <p>18 presented and the sponsor's interpretation of those</p> <p>19 results and conclusions. And that's what this is --</p> <p>20 Q. Okay.</p> <p>21 A. -- for the CLASS trial.</p> <p>22 Q. And looking at pages 6 and 7, those are</p> <p>23 the -- the summary tables from the synopsis.</p> <p>24 What's the point of the synopsis and the</p>
<p>126</p> <p>1 Q. I'd be glad to. Let me give you what has</p> <p>2 been marked as Plaintiffs' Exhibit 66.</p> <p>3 Could you please take a look at</p> <p>4 Plaintiffs' Exhibit 66. And obviously, it's a long</p> <p>5 document, but if you feel comfortable identifying</p> <p>6 generally what this document is for the record, I'd</p> <p>7 ask you to do so.</p> <p>8 And specifically, I think the</p> <p>9 information, you know, you want to look at is on</p> <p>10 pages 6 and 7, the summary of CSUGIE incidents, and</p> <p>11 on the next page, page 7, the summary of the CSUGIEs</p> <p>12 and GDU incidents combined at six months and the</p> <p>13 entire study period.</p> <p>14 And -- and I mean, you -- you certainly</p> <p>15 have the right to review the whole document, but</p> <p>16 it's a lengthy document and we were sort of in the</p> <p>17 middle of a --</p> <p>18 A. Right.</p> <p>19 Q. -- question. So --</p> <p>20 A. Right.</p> <p>21 Q. So if I could ask you, does this appear</p> <p>22 to be the final -- at least the first 200-and-some</p> <p>23 pages or -- I'm sorry, let me give you the exact</p> <p>24 number -- so at least the first 216 pages of the</p>	<p>128</p> <p>1 summary tables?</p> <p>2 A. In our -- in the Searle organization, the</p> <p>3 purpose of the synopsis is to present the salient</p> <p>4 features of the study report, meaning the high-level</p> <p>5 features.</p> <p>6 Q. Is that also referred to as top-line</p> <p>7 data, sometimes?</p> <p>8 A. I don't refer to it as top line because</p> <p>9 as you can see, there's a lot of information in this</p> <p>10 synopsis. And to call all of it top line is a very</p> <p>11 subjective comment.</p> <p>12 Q. Well, let's look at pages 6 and 7,</p> <p>13 Tables 1 through 4.</p> <p>14 Is that the top-line data of the CLASS</p> <p>15 study?</p> <p>16 A. I just don't know -- I don't understand</p> <p>17 what you mean by "top line."</p> <p>18 Q. Okay. Well, we'll --</p> <p>19 A. I can talk to you about other things, but</p> <p>20 top line isn't a phrase I use --</p> <p>21 Q. Okay. Let's not use it, then.</p> <p>22 A. -- when I talk about a study.</p> <p>23 Q. Tables 1 through 4, is that the</p> <p>24 salient -- you know, if you were really going to put</p>



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<p>129</p> <p>1 it down to the most important or some of the most</p> <p>2 important things that occur in the CLASS study,</p> <p>3 does -- do Tables 1 through 4 summarize much of</p> <p>4 that?</p> <p>5 A. Yes, I would agree.</p> <p>6 Q. Okay. And then Table 1 is a summary of</p> <p>7 the CSUGIEs or complicated ulcer incidents for the</p> <p>8 first six months of the trial, correct?</p> <p>9 A. Well, to go back to some of our original</p> <p>10 comments when we started, it's CSUGIEs --</p> <p>11 Q. CSUGIEs.</p> <p>12 A. -- not CSUGIEs.</p> <p>13 Q. Can we just call them complicated</p> <p>14 ulcers --</p> <p>15 A. Fine.</p> <p>16 Q. -- even though --</p> <p>17 A. Okay.</p> <p>18 Q. -- it says CSUGIEs on there?</p> <p>19 A. CSUGIEs are --</p> <p>20 Q. CSUGIE --</p> <p>21 A. Yeah. Okay.</p> <p>22 Q. It -- it -- because it's stuck in my mind</p> <p>23 to call it that way.</p> <p>24 A. I know.</p>	<p>131</p> <p>1 symptomatic or GDUs together, and Table 3 is the</p> <p>2 first six months; is that correct?</p> <p>3 A. That's correct.</p> <p>4 Q. And then Table 4 is the entire study</p> <p>5 period?</p> <p>6 A. That's correct.</p> <p>7 Q. And it's got P Values comparing -- all</p> <p>8 four of these tables have P Values comparing</p> <p>9 Celebrex to Diclofenac by itself, Ibuprofen by</p> <p>10 itself and the two NSAIDs together; is that correct?</p> <p>11 A. That's correct.</p> <p>12 Q. Okay. And getting back to my question,</p> <p>13 so if you get back to that sentence in Exhibit 67</p> <p>14 that we were talking about, the first sentence in</p> <p>15 the third paragraph, if you look at Tables 1</p> <p>16 through 4, just the comparison with Diclofenac,</p> <p>17 there's 8 different comparisons in Tables 1 through</p> <p>18 4; is that correct, comparing Celebrex to Diclofenac</p> <p>19 by itself?</p> <p>20 A. I'm sorry, say it again. You're going</p> <p>21 pretty fast --</p> <p>22 Q. Yeah, I'm --</p> <p>23 A. -- in terms of throwing numbers out.</p> <p>24 Q. I'm real sorry. Yeah.</p>
<p>130</p> <p>1 Q. But you understand Table 1 is a summary</p> <p>2 of the complicated ulcers at six months; is that</p> <p>3 correct?</p> <p>4 A. For over the first six months, yes.</p> <p>5 Q. Right. And it -- and it breaks down</p> <p>6 P Values, comparing Celebrex to Diclofenac by</p> <p>7 itself, Ibuprofen by itself and then the two</p> <p>8 together?</p> <p>9 A. Yes.</p> <p>10 Q. And then it also has a table doing the</p> <p>11 same -- same thing for nonaspirin, the nonaspirin</p> <p>12 group, the people who didn't also take aspirin?</p> <p>13 A. For the -- yes, Table 1 has that for the</p> <p>14 first six months.</p> <p>15 Q. And then Table 2 is the entire study,</p> <p>16 those same comparisons I just referenced for the</p> <p>17 entire study period?</p> <p>18 A. Yes, Table 2 does that.</p> <p>19 Q. So it's got the comparisons, the</p> <p>20 Diclofenac, Ibuprofen and both, and for everybody</p> <p>21 and the nonaspirin group for the entire study?</p> <p>22 A. Correct.</p> <p>23 Q. And then Table 3 is this combined</p> <p>24 endpoint of the complicated ulcers and the</p>	<p>132</p> <p>1 So Table 1, 2, 3 and 4, there's -- each</p> <p>2 one of those -- each one of those four tables has</p> <p>3 two different comparisons with Diclofenac itself?</p> <p>4 A. Right.</p> <p>5 Q. And provides a -- a P Value, correct?</p> <p>6 A. That's what these tables show.</p> <p>7 Q. And what's a Log-Rank P Value? Can you</p> <p>8 just give us the simple version of what a Log-Rank</p> <p>9 P Value is?</p> <p>10 A. So I'm not a statistician, so I'm</p> <p>11 speaking it from a general clinical point of view.</p> <p>12 A P Value tells you -- gives you an idea</p> <p>13 of the probability that you are either right or</p> <p>14 wrong -- or the -- the results you have obtained</p> <p>15 from the trial are either correct or incorrect in</p> <p>16 terms of what is really true.</p> <p>17 Q. Right. And for the purposes of CLASS, in</p> <p>18 order for a P Value to be statistically significant,</p> <p>19 it had to be less than .05; is that correct?</p> <p>20 A. For it to be statistically significantly</p> <p>21 different, it had to be less than .05, that's</p> <p>22 correct.</p> <p>23 Q. Right. And if we look in Tables 1</p> <p>24 through 4 of Exhibit 66, the eight different</p>



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<p style="text-align: center;">133</p> <p>1 comparisons with Diclofenac, not a single one of 2 those comparisons between Celebrex and Diclofenac 3 were statistically significant; is that correct, 4 sir?</p> <p>5 A. These numbers are -- are greater than 6 .05. But I think it has to be pointed out that 7 P Values, in and of themselves, do not necessarily 8 tell you whether the results of the study are 9 meaningful or not.</p> <p>10 Q. Right. But you could --</p> <p>11 A. You have to interpret them in the context 12 of what you know about all of the data.</p> <p>13 Q. You -- you couldn't make a claim that the 14 difference was due to something other than chance, 15 the way this study was set up, unless the P Value 16 was less than .05; is that correct, sir?</p> <p>17 MR. HOFF: Objection to form.</p> <p>18 BY THE WITNESS:</p> <p>19 A. I'm sorry, could you repeat the question.</p> <p>20 BY MR. SAHAM:</p> <p>21 Q. You couldn't make -- and is it -- is it 22 fair to say if something is not statistically 23 significant, it could have been caused as a result 24 of just chance or a random --</p>	<p style="text-align: center;">135</p> <p>1 P Value at all.</p> <p>2 Q. Right. All I'm getting at is, per the 3 protocol and per the study, if you didn't have a 4 P Value of less than .05, like when you were 5 comparing Celebrex to Diclofenac, you couldn't 6 claim, at least on that endpoint, that Celebrex was 7 better on the particular endpoint being compared; is 8 that correct, sir?</p> <p>9 MR. WEISS: I objection to the form.</p> <p>10 MR. HOFF: Objection to form.</p> <p>11 BY THE WITNESS:</p> <p>12 A. What I'm struggling with is the word 13 "claim." You couldn't say that the P Value was 14 greater than .05. But I could say, because of 15 confounding circumstances, although that P Value is 16 greater than .05 and for other things that we know 17 about the study, I would -- I could possibly claim I 18 think treatment groups are different.</p> <p>19 BY MR. SAHAM:</p> <p>20 Q. Right. But you -- you can't make a claim 21 of statistical significance per the protocol unless 22 the P Value was less than .05; is that correct, sir?</p> <p>23 A. Statistical significance -- I would agree 24 that you cannot say something is statistically --</p>
<p style="text-align: center;">134</p> <p>1 A. If it's --</p> <p>2 Q. -- occurrence?</p> <p>3 A. -- not statistically significant, it 4 could have been caused by chance? No, it could have 5 been caused by imbalances in treatment groups.</p> <p>6 Q. Well, but you can't conclude --</p> <p>7 MR. HOFF: Wait, wait, wait.</p> <p>8 BY MR. SAHAM:</p> <p>9 Q. -- it was caused --</p> <p>10 MR. HOFF: Wait, wait, wait a second. Wait a 11 second. You have a habit of doing this. I know 12 you're eager to answer your -- ask your questions, 13 but I'm not sure if he finished answering --</p> <p>14 BY MR. SAHAM:</p> <p>15 Q. I'm sorry. Are you done, sir --</p> <p>16 MR. HOFF: -- the question.</p> <p>17 BY MR. SAHAM:</p> <p>18 Q. -- with that answer?</p> <p>19 A. So what I'm saying is, you can get 20 P Values, whether they're statistically significant 21 or not statistically significant, that -- that are 22 not just by chance alone. They are due to aspects 23 of the study and things that happened in the study 24 that confounds your ability to determine that</p>	<p style="text-align: center;">136</p> <p>1 that the P Value is less than .05 when the P Value 2 is -- that you see is greater than .05.</p> <p>3 Q. So -- so therefore, none of these eight 4 comparisons on pages 6 and 7 have a P Value less 5 than .05 when Celebrex is compared to Diclofenac; is 6 that correct, sir?</p> <p>7 A. That is correct.</p> <p>8 Q. So therefore, you couldn't claim, for the 9 purposes of CLASS, that there is a statistically 10 significant difference on any of these eight 11 comparisons between Celebrex and Diclofenac; is that 12 correct, sir?</p> <p>13 A. Again, I will -- I think the -- the 14 operational word is "statistically significant." 15 But what we do is, when we interpret results, it is 16 not just based on statistical methodology. It's 17 based on our clinical understanding of all the data.</p> <p>18 Q. Right. That aside -- I'm just talking 19 about statistical significance.</p> <p>20 A. Okay. As long as we understand --</p> <p>21 Q. Totally, sir.</p> <p>22 A. -- that we're talking about just -- just 23 a P Value and results cannot be interpreted just 24 based on a P Value. In that context, I would agree.</p>



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<p>137</p> <p>1 Q. So you're agreeing with me you couldn't</p> <p>2 make a claim that there is a statistically</p> <p>3 significant difference on any of these eight</p> <p>4 endpoints between Celebrex and Diclofenac?</p> <p>5 A. I would rather we not use the word</p> <p>6 "claim." We could not say that we were</p> <p>7 statistically different.</p> <p>8 Q. Okay. I'll -- I'll repeat the question.</p> <p>9 You can't say, on any of these eight</p> <p>10 endpoints, that the comparison between Diclofenac</p> <p>11 and Celebrex was statistically significant; is that</p> <p>12 correct, sir?</p> <p>13 A. I agree.</p> <p>14 Q. Okay. And if you read Plaintiffs'</p> <p>15 Exhibit 67, the press release, it does not tell the</p> <p>16 reader that of these eight salient comparisons</p> <p>17 contained on pages 6 and 7 of Exhibit 66, that there</p> <p>18 was no statistically significant difference between</p> <p>19 Celebrex and Diclofenac; is that correct, sir?</p> <p>20 A. That is correct, but we couldn't anyway.</p> <p>21 Because in this press release, my understanding is</p> <p>22 we can only present results that were presented by</p> <p>23 Dr. Silverstein at ACP.</p> <p>24 Q. And then you -- by that reasoning, you</p>	<p>139</p> <p>1 because that's the first thing and the biggest thing</p> <p>2 and the most important thing about that study, as</p> <p>3 agreed in the design with the FDA, as agreed with</p> <p>4 everybody involved. That is the first thing, the</p> <p>5 major comparison that we are interested in this</p> <p>6 study.</p> <p>7 Q. My --</p> <p>8 A. As -- as is the case, that is the first</p> <p>9 thing that you do present when you go public,</p> <p>10 public, when you present it.</p> <p>11 And that is what Dr. Silverstein's</p> <p>12 presentation was the focus of, and that's what he</p> <p>13 presented.</p> <p>14 Q. My question to you, though:</p> <p>15 Dr. Silverstein didn't tell any of the doctors in</p> <p>16 his presentation at ACP that there was no</p> <p>17 statistically significant difference between</p> <p>18 Celebrex and Diclofenac on either the combined</p> <p>19 endpoint or the complicated ulcer endpoint; is that</p> <p>20 correct, sir?</p> <p>21 A. In the context of what I just said, that</p> <p>22 was not part of the presentation, correct.</p> <p>23 MR. SAHAM: Okay. We need to take a break to</p> <p>24 change the tape now.</p>
<p>138</p> <p>1 would agree with me that Dr. Silverstein didn't tell</p> <p>2 any of the doctors present at ACP that there was no</p> <p>3 statistically significant comparison between</p> <p>4 Celebrex and Diclofenac at either the complicated</p> <p>5 ulcer endpoint or the combined complicated and</p> <p>6 symptomatic ulcer endpoint; is that correct, sir?</p> <p>7 A. Okay. Let's -- I need to go back to what</p> <p>8 was the intent of the presentation --</p> <p>9 Q. I'm entitled to an answer to my question.</p> <p>10 A. And I'm trying to answer your question.</p> <p>11 The intent of the -- this -- the ACP</p> <p>12 presentation by Dr. Silverstein was the first public</p> <p>13 presentation of the results of CLASS.</p> <p>14 In the -- in the first public</p> <p>15 presentation any time of a study, it's, you present</p> <p>16 what is the -- the primary objective that you are</p> <p>17 looking at. And the primary objective, it was</p> <p>18 always understood, was comparing Celebrex to the</p> <p>19 group, combined group, of Ibuprofen and Diclofenac.</p> <p>20 That was the understanding of the overall hypothesis</p> <p>21 of the study, how does Celebrex look to those</p> <p>22 combined.</p> <p>23 It was the intent of that presentation to</p> <p>24 present, as a focus, the results of that analysis,</p>	<p>140</p> <p>1 THE WITNESS: Okay.</p> <p>2 THE VIDEOGRAPHER: Going off the video record</p> <p>3 at 12:03 p.m.</p> <p>4 This is the end of Tape No. 2.</p> <p>5 (WHEREUPON, a short recess was</p> <p>6 had.)</p> <p>7</p> <p>8 THE VIDEOGRAPHER: Going back on the video</p> <p>9 record at 12:12 p.m.</p> <p>10 This is the beginning of Tape No. 3.</p> <p>11 (WHEREUPON, a certain document was</p> <p>12 marked Plaintiffs' Deposition</p> <p>13 Exhibit No. 256, for identification,</p> <p>14 as of 12/10/2010.)</p> <p>15 BY MR. SAHAM:</p> <p>16 Q. Sir, I'm showing you what's been marked</p> <p>17 as Plaintiffs' Exhibit 256. It's a one-page</p> <p>18 document bearing Bates number DEFS 00120490. And</p> <p>19 this also indicates that it was produced from your</p> <p>20 files, your electronic custodial documents.</p> <p>21 I'd ask you if you recognize it?</p> <p>22 A. I do not.</p> <p>23 Q. Okay. But you don't dispute that this</p> <p>24 came from your files?</p>



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<p>141</p> <p>1 A. I -- either way, I don't know if it was.</p> <p>2 Q. You may have drafted it or received it?</p> <p>3 You don't know?</p> <p>4 A. I don't know.</p> <p>5 Q. Okay. And I'm -- I want to focus on .5.</p> <p>6 It says, "How do we defend the pooled analysis of</p> <p>7 NSAIDs? Did not beat diclo, therefore cannot imply</p> <p>8 that we did by the pooled analysis."</p> <p>9 It is accurate that you didn't -- you</p> <p>10 didn't beat Diclofenac on any of the four -- or any</p> <p>11 of the eight comparisons we were looking at on</p> <p>12 pages 6 and 7 of Exhibit 66, correct?</p> <p>13 MR. HOFF: Objection to form.</p> <p>14 BY MR. SAHAM:</p> <p>15 Q. When I say "you," Celebrex didn't beat</p> <p>16 Diclofenac on any --</p> <p>17 MR. HOFF: Objection --</p> <p>18 BY MR. SAHAM:</p> <p>19 Q. -- of those eight comparisons?</p> <p>20 MR. HOFF: Objection to form.</p> <p>21 BY THE WITNESS:</p> <p>22 A. I want to go back to what the intent of</p> <p>23 the study was and how you get to the Diclofenac</p> <p>24 comparisons.</p>	<p>143</p> <p>1 But go ahead if you've got more to say --</p> <p>2 MR. HOFF: You've got a pending motion to</p> <p>3 strike that some judge some day may consider.</p> <p>4 BY MR. SAHAM:</p> <p>5 Q. And if it would make more sense,</p> <p>6 Dr. Geis, to actually read what the protocol says</p> <p>7 about how the comparison's done, will that make this</p> <p>8 more efficient? If you don't want to do it, fine,</p> <p>9 but I would recommend that we do it because we have</p> <p>10 it right here as a marked exhibit.</p> <p>11 A. I'd like to say what I have to say, and</p> <p>12 I'll try to be, you know, clear. And then we can</p> <p>13 possibly move to that.</p> <p>14 But the -- the -- the rules were that for</p> <p>15 the primary endpoint of the study, which was the</p> <p>16 comparison of Celebrex to the combined group of</p> <p>17 Diclofenac and Ibuprofen for ulcer complications, if</p> <p>18 you were not statistically different for the</p> <p>19 combined group and you step down to do the</p> <p>20 comparison of Celebrex versus Diclo alone and</p> <p>21 Celebrex versus Ibu alone, you couldn't make the</p> <p>22 claim. Even though you were statistically</p> <p>23 significant for either of those, you could not make</p> <p>24 that claim.</p>
<p>142</p> <p>1 As I said earlier, that the overriding</p> <p>2 objective of the study was to compare Celebrex to</p> <p>3 the combined group of Diclofenac and Ibuprofen in</p> <p>4 terms of ulcer complications and -- symptomatic</p> <p>5 ulcers and ulcer complications. The statistical</p> <p>6 plan, there were statistical rules for the primary</p> <p>7 endpoint, which were -- was ulcer complications.</p> <p>8 BY MR. SAHAM:</p> <p>9 Q. I don't want to interrupt you. Why don't</p> <p>10 we look at those rules. If you get out</p> <p>11 Exhibit 77 and turn to page --</p> <p>12 MR. HOFF: Well, wait a second. You are</p> <p>13 interrupting him because he's in the middle --</p> <p>14 MR. SAHAM: Well, but I'm going to move to</p> <p>15 strike. It's nonresponsive.</p> <p>16 MR. HOFF: No, you're not the judge, so...</p> <p>17 MR. SAHAM: I only got seven hours.</p> <p>18 MR. HOFF: Wait. You don't have robes, so you</p> <p>19 can move all you want. It isn't being granted. He</p> <p>20 is answering your question. You should let him</p> <p>21 finish, then you can follow up with whatever you</p> <p>22 want to show him.</p> <p>23 MR. SAHAM: Okay. And I'm going to move to</p> <p>24 strike as nonresponsive.</p>	<p>144</p> <p>1 Q. And that's because the null hypothesis is</p> <p>2 maintained if you don't beat the two combined; is</p> <p>3 that correct, sir?</p> <p>4 MR. HOFF: Well, first of all, did you finish</p> <p>5 ans- --</p> <p>6 THE WITNESS: No.</p> <p>7 MR. HOFF: -- your answer?</p> <p>8 BY THE WITNESS:</p> <p>9 A. So -- so -- so in that context, when</p> <p>10 you -- there were rules about stepping down in</p> <p>11 looking at Celebrex versus the individual NSAIDs and</p> <p>12 the claims you could make if you did not reach the</p> <p>13 primary endpoint for the combined group of Ibuprofen</p> <p>14 and Diclofenac.</p> <p>15 We did not -- we were not -- we did not</p> <p>16 beat Ibuprofen and Diclofenac combined for the</p> <p>17 primary endpoint. And although we stepped down, as</p> <p>18 you see, we knew you could not make claims based on</p> <p>19 the stepdown.</p> <p>20 So that's what I wanted to say.</p> <p>21 BY MR. SAHAM:</p> <p>22 Q. Could you take a look at Exhibit 77, the</p> <p>23 protocol that we looked at earlier, and specifically</p> <p>24 page 30. And I think this is what you're</p>



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<p>145</p> <p>1 describing -- but you can certainly correct me if</p> <p>2 I'm wrong -- the top paragraph on page 30 of 36.</p> <p>3 MR. HOFF: Did you say 67 or 77?</p> <p>4 MR. SAHAM: I said 77, yeah.</p> <p>5 MR. HOFF: Okay. Thank you.</p> <p>6 BY MR. SAHAM:</p> <p>7 Q. And the second sentence there says, "A</p> <p>8 stepwise procedure will be used to strongly control</p> <p>9 the type-I error. In this procedure, the first step</p> <p>10 is to test the overall hypothesis, whether Celecoxib</p> <p>11 and the pooled NSAIDs are different. If the test is</p> <p>12 not significant, then null hypothesis is retained</p> <p>13 and the procedure stops."</p> <p>14 Is that -- did I accurately read what the</p> <p>15 protocol says on the -- at least the first part of</p> <p>16 the stepwise procedure of analyzing the primary</p> <p>17 endpoint?</p> <p>18 A. Yes, you accurately read that.</p> <p>19 Q. Okay. So that means if you don't beat</p> <p>20 the two combined, the null hypothesis is retained.</p> <p>21 And what was the null hypothesis?</p> <p>22 A. The null hypothesis for, in this case,</p> <p>23 the comparison of Celebrex versus the two NSAIDs</p> <p>24 com- -- together for the primary endpoint of ulcer</p>	<p>147</p> <p>1 to what our thinking was and what we did.</p> <p>2 Q. All I'm trying to say is, if you look at</p> <p>3 the comparisons, the salient comparisons -- I think</p> <p>4 you described them -- or some of the salient</p> <p>5 comparisons that are summarized in the synopsis,</p> <p>6 Tables 1 through 4 -- and we talked about this</p> <p>7 earlier -- that Celebrex didn't beat Diclofenac or</p> <p>8 there couldn't be a claim that Celebrex beat</p> <p>9 Diclofenac on any of those eight comparisons?</p> <p>10 A. Statistically, the P Values for the</p> <p>11 comparisons -- so, first of all, for the ulcer</p> <p>12 complications, we were not statistically different.</p> <p>13 So the stepdown says you can't make any</p> <p>14 claims once you step down. Okay. Even though we</p> <p>15 did step down, the P Value, in and of itself,</p> <p>16 statistically, for Diclofenac was greater than .05.</p> <p>17 Q. Which means it wasn't statistically</p> <p>18 significant?</p> <p>19 A. Statistically, correct.</p> <p>20 Q. Now I would like --</p> <p>21 A. But that is not the -- but that's not the</p> <p>22 only piece of information you use to interpret the</p> <p>23 results of a study.</p> <p>24 Q. But you couldn't say it was statistically</p>
<p>146</p> <p>1 complications would be that you -- you cannot make</p> <p>2 the claim -- you would retain the null hypothesis</p> <p>3 that the two groups, Celebrex versus the NSAIDs</p> <p>4 together, are not different --</p> <p>5 Q. Okay.</p> <p>6 A. -- statistically.</p> <p>7 Q. Okay. Is it also correct that as part of</p> <p>8 the CLASS study -- and specifically we've looked at</p> <p>9 the combined endpoint and the primary endpoint of</p> <p>10 complicated ulcers -- that Celebrex did not beat</p> <p>11 Diclofenac on the eight comparisons talked about on</p> <p>12 pages 6 and 7 in Tables 1 through 4 of Exhibit 66?</p> <p>13 MR. HOFF: Can you read back that question?</p> <p>14 (WHEREUPON, the record was read by</p> <p>15 the reporter.)</p> <p>16 THE WITNESS: I apologize, could you read it</p> <p>17 again, really. I mean, because there's a lot of</p> <p>18 stuff in there. There's a lot of things here, and I</p> <p>19 want to make sure.</p> <p>20 BY MR. SAHAM:</p> <p>21 Q. I -- I can ask it simpler, if that would</p> <p>22 be better for you, sir.</p> <p>23 A. Right. But I don't want to give an</p> <p>24 answer that can be generalized that is not accurate</p>	<p>148</p> <p>1 significant?</p> <p>2 A. Statistically. Technically,</p> <p>3 statistically we could not say that.</p> <p>4 Q. Now, moving down to the next sentence, we</p> <p>5 spent quite a bit of time on that first sentence in</p> <p>6 the third paragraph, but the next sentence says,</p> <p>7 number --</p> <p>8 A. Help me.</p> <p>9 Q. -- Exhibit 67, the press release, what we</p> <p>10 stipulated is the press release, that Jonathan Hoff,</p> <p>11 partner at Cadwalader, has stipulated was the press</p> <p>12 release --</p> <p>13 A. Page 2 --</p> <p>14 Q. -- page 2, Paragraph 3, sentence 2.</p> <p>15 A. Okay.</p> <p>16 Q. So the one we were talking about, the</p> <p>17 first sentence in that paragraph, for a long time.</p> <p>18 Now we're going to talk about the second</p> <p>19 sentence, hopefully for not quite as long, but we're</p> <p>20 still going to talk about it.</p> <p>21 And that second sentence, I'm going to</p> <p>22 read it into the record. It says, "Celebrex was</p> <p>23 also associated with numerically fewer ulcer</p> <p>24 complications than the NSAID comparators among all</p>





<p>149</p> <p>1 patients, and 64 percent fewer of these serious</p> <p>2 events among nonaspirin users, a statistically</p> <p>3 significant difference."</p> <p>4 Do you see that?</p> <p>5 A. I do.</p> <p>6 Q. And that claim is only valid if you</p> <p>7 looked at the 6-month data, that claim of</p> <p>8 statistical significance; is that correct, sir?</p> <p>9 A. I'd have to look.</p> <p>10 It appears that this is referring to</p> <p>11 the -- what people referred to as the 6-month</p> <p>12 analysis.</p> <p>13 Q. And that claim of statistical</p> <p>14 significance for the nonaspirin group for ulcer</p> <p>15 complications, that comparison was not statistically</p> <p>16 significant for the entire study period; is that</p> <p>17 correct, sir?</p> <p>18 A. So let me go back.</p> <p>19 This press release is presenting what</p> <p>20 Fred Silverstein presented at American College of</p> <p>21 Physicians. So it's based on that. Fred</p> <p>22 Silverstein presented numbers related to the 6-month</p> <p>23 analysis, however, acknowledged that there was data</p> <p>24 beyond six months. But due to confounding issues</p>	<p>151</p> <p>1 A. Statistically, but statistics are not the</p> <p>2 only thing for interpreting the results of a</p> <p>3 clinical trial.</p> <p>4 Q. But the sentence --</p> <p>5 A. The P Value was not considered valid for</p> <p>6 interpretation in my view, beyond six months.</p> <p>7 Q. But the sentence I just read to you, the</p> <p>8 last phrase says, "A statistically significant</p> <p>9 difference," correct?</p> <p>10 A. With respect to what is presented right</p> <p>11 here with -- the -- the sentence that says, the</p> <p>12 numerically fewer ulcer complications than NSAIDs</p> <p>13 comparators, that's correct, and that is for the set</p> <p>14 of data that is considered valid.</p> <p>15 So they're saying we're presenting the</p> <p>16 valid data. We have reasons why this is valid.</p> <p>17 And, oh, by the way, statistically, it was</p> <p>18 significant.</p> <p>19 Q. And this press release doesn't tell</p> <p>20 anyone who reads it that if you looked at the entire</p> <p>21 study data, that statistically significant</p> <p>22 difference did not continue; is that correct, sir?</p> <p>23 A. Well, it presents what Dr. Silverstein</p> <p>24 presented. Dr. Silverstein presented this 6-month</p>
<p>150</p> <p>1 related to how this study was conducted, the data</p> <p>2 beyond six months was not considered valid.</p> <p>3 So he presented the valid results of the</p> <p>4 study. That's what he presented in his</p> <p>5 presentation. As I said earlier, my understanding</p> <p>6 is, you can, in the press release, only talk about</p> <p>7 the data that was presented in the presentation.</p> <p>8 So this data reflects Fred Silverstein's</p> <p>9 presentation, which reflects what is considered the</p> <p>10 valid analysis of the study.</p> <p>11 Q. Okay. And I've -- I've got sort of two</p> <p>12 short questions to follow up on that.</p> <p>13 You would agree with me that this claim</p> <p>14 of statistical significance with respect to the</p> <p>15 nonaspirin subgroup for complicated ulcers did not</p> <p>16 hold for the entire study period; is that correct,</p> <p>17 sir?</p> <p>18 A. If you are just talking about P Values,</p> <p>19 the P Value for the longer term analysis, which now</p> <p>20 is almost meaningless because you are including an</p> <p>21 entire set of data that's invalid, that P Value,</p> <p>22 yes, was greater than .05.</p> <p>23 Q. So therefore, you couldn't say it was</p> <p>24 statistically significant, correct, sir?</p>	<p>152</p> <p>1 analysis, which was the valid analysis. He</p> <p>2 acknowledged that data beyond six months was not</p> <p>3 valid. So --</p> <p>4 Q. Could you look --</p> <p>5 A. -- he presented what he -- he presented</p> <p>6 in his data.</p> <p>7 Q. Could you look back at Exhibit 252, the</p> <p>8 slides from Dr. Silverstein's presentation at -- at</p> <p>9 American College of Physicians.</p> <p>10 Can you show me the slide that points out</p> <p>11 that there was a confounding -- there was</p> <p>12 confoundings to the data after six months, or that</p> <p>13 there was biases that required the data to be</p> <p>14 excluded after six months?</p> <p>15 A. So I am on exhibit -- I believe you call</p> <p>16 these exhibits at the bottom right-hand corner?</p> <p>17 Q. 252.</p> <p>18 A. Yes. And there is a set of slides which</p> <p>19 I don't recognize specifically, but based on the</p> <p>20 e-mail, it appears that these were finals that Fred</p> <p>21 Silverstein presented.</p> <p>22 However, I do have some question about</p> <p>23 the specific set -- the set you gave me because</p> <p>24 there's something wrong with some of these slides</p>



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<p>153</p> <p>1 that I can't believe Silverstein used them.</p> <p>2 But having said that, there is no slide</p> <p>3 that shows data beyond six months. However, I was</p> <p>4 at that presentation, and it was specifically said</p> <p>5 that the data beyond six months -- there was data</p> <p>6 beyond six months. There was -- and -- and it was</p> <p>7 confounded for a variety of reasons.</p> <p>8 And that was heard by the audience, and</p> <p>9 it was heard -- I mean, actually, I think there were</p> <p>10 analyst reports which talk about that Silverstein</p> <p>11 said there was longer data, but he only presented</p> <p>12 six months' data.</p> <p>13 So although there isn't a slide, I'm</p> <p>14 confident -- I know it was stated and he said it was</p> <p>15 nonvalid after six months.</p> <p>16 Q. You would agree with me that turning back</p> <p>17 to the press release, Exhibit 67, there's no</p> <p>18 statement addressing that the data after six months</p> <p>19 was confounded; is that correct, sir?</p> <p>20 A. There is -- he's -- the -- the press</p> <p>21 release is presenting what Dr. Silverstein</p> <p>22 presented, and it -- and it refers to data for six</p> <p>23 months.</p> <p>24 Q. But it doesn't say anything that the --</p>	<p>155</p> <p>1 significant on the complicated ulcer primary</p> <p>2 endpoint, it doesn't in any way reveal the press</p> <p>3 release itself, in no way reveals that that</p> <p>4 conclusion could only be based on the 6-month data;</p> <p>5 is that correct, sir?</p> <p>6 A. I disagree because it is -- this data is</p> <p>7 referring to Fred Silverstein's presentation at ACP.</p> <p>8 Q. Fred Silverstein's presentation at ACP</p> <p>9 was not circulated via the wire services on</p> <p>10 April 17, 2000, was it, sir?</p> <p>11 A. I can't speak to that because I don't</p> <p>12 know. But I know that the introductory paragraph</p> <p>13 refers to, as presented at ACP. And so it is the</p> <p>14 data at ACP that is presented here.</p> <p>15 Q. My question to you --</p> <p>16 A. And that's what I would do as a</p> <p>17 reviewer -- or a reader of this, go, what did he</p> <p>18 present? And that would be --</p> <p>19 Q. My question to you, sir -- and I'm</p> <p>20 entitled to an answer to this question -- a reader</p> <p>21 of this press release, if you've read it, a</p> <p>22 securities analyst, whoever, me, anybody who read</p> <p>23 this off the wire services would not know that the</p> <p>24 claim of statistical significance -- just based on</p>
<p>154</p> <p>1 the entire study data was not shared because it was</p> <p>2 confounded; is that correct, sir?</p> <p>3 A. This press release -- although Fred</p> <p>4 Silverstein said it, this press release does not say</p> <p>5 that.</p> <p>6 Q. And this press release, if you look down</p> <p>7 to the paragraph after the one that we were looking</p> <p>8 at on page 2, the fourth paragraph, the first</p> <p>9 sentence says, quote, This rigorous outcomes trial</p> <p>10 set the bar higher than previous study -- well, let</p> <p>11 me read that again because I think I misread it.</p> <p>12 "This rigorous outcomes trial set the bar</p> <p>13 higher than any previous study of its kind. It</p> <p>14 included a large number of patients who received</p> <p>15 four times the recommended OA dose of Celebrex for</p> <p>16 up to 13 months."</p> <p>17 That's what the press release says,</p> <p>18 correct?</p> <p>19 A. The press release is quoting what Fred</p> <p>20 Silverstein said, and, yes, that's what this</p> <p>21 sentence says.</p> <p>22 Q. Okay. So this press release in no way</p> <p>23 indicates that the sentence we were reading earlier</p> <p>24 about the nonaspirin subgroup being statistically</p>	<p>156</p> <p>1 this document, the reader would not know that the</p> <p>2 claim of statistical significance for the nonaspirin</p> <p>3 subgroup for complicated ulcers, the claim of</p> <p>4 statistical significance could only be made based on</p> <p>5 the 6-month data; is that correct, sir?</p> <p>6 MR. HOFF: Objection to form.</p> <p>7 BY THE WITNESS:</p> <p>8 A. I can't tell you what someone else would</p> <p>9 know. I can only tell you, when I read this, what</p> <p>10 it says to me.</p> <p>11 BY MR. SAHAM:</p> <p>12 Q. The -- the person who conducted the</p> <p>13 study, you're the person --</p> <p>14 MR. HOFF: Objection to form.</p> <p>15 BY MR. SAHAM:</p> <p>16 Q. -- who conducted the study or were -- was</p> <p>17 a -- were a supervisor of the studies?</p> <p>18 I'll strike that question.</p> <p>19 My question to you, Exhibit 67, you've</p> <p>20 been designated by Pharmacia with respect to the</p> <p>21 issuance of this press release --</p> <p>22 MR. HOFF: Only -- only with respect to the --</p> <p>23 the process for drafting it and who was involved in</p> <p>24 it.</p>



<p>157</p> <p>1 MR. SAHAM: Well -- well --</p> <p>2 MR. HOFF: He's not -- your -- your -- your</p> <p>3 topic does not contemplate the discussions about the</p> <p>4 content of the press release.</p> <p>5 BY MR. SAHAM:</p> <p>6 Q. The topic of the press release is -- --</p> <p>7 or that -- what you've been designated as -- and I</p> <p>8 think you've testified to this already, but I'll</p> <p>9 read it into the record -- quote, the issuance of</p> <p>10 the press release, including, but not limited to,</p> <p>11 the process for and individuals involved with</p> <p>12 drafting, editing and approving the press release.</p> <p>13 You've been designated to testify on that</p> <p>14 topic, correct, sir?</p> <p>15 A. Yes.</p> <p>16 Q. And my question to you, sir, as both</p> <p>17 Steven Geis and as that designee, the text of</p> <p>18 Exhibit 67, the words contained within Exhibit 67</p> <p>19 does -- do not disclose that this claim of</p> <p>20 statistical significance for the nonaspirin subgroup</p> <p>21 for complicated ulcers is based on 6-month data; is</p> <p>22 that correct, sir?</p> <p>23 MR. HOFF: Objection to form, sir.</p> <p>24 BY THE WITNESS:</p>	<p>159</p> <p>1 they could. All I know is the process of how press</p> <p>2 releases are put together, what is appropriate for a</p> <p>3 press release.</p> <p>4 And as I read it, and as I have read many</p> <p>5 press releases before for other companies, when it</p> <p>6 says, the findings presented at this place, you go</p> <p>7 to that place to get the detail that you need --</p> <p>8 Q. Other than that --</p> <p>9 A. -- if you have a question.</p> <p>10 Q. Other than that sentence that says, "The</p> <p>11 findings presented," is there any other spot in the</p> <p>12 press release that you believe reveals to the reader</p> <p>13 of the press release that the statement about</p> <p>14 statistical significance in the nonaspirin subgroup</p> <p>15 for complicated ulcers was based on 6-month data?</p> <p>16 A. I'll have to read this again.</p> <p>17 That is the spot. I don't find another</p> <p>18 reference.</p> <p>19 Q. Okay. Looking at Exhibit 67, there's no</p> <p>20 reference in this -- you just read it a couple</p> <p>21 times.</p> <p>22 There's no reference in here to the FDA</p> <p>23 alternative definition of complicated ulcer, is</p> <p>24 there, in this press release or in Dr. Silverstein's</p>
<p>158</p> <p>1 A. This data, it's my understanding of the</p> <p>2 process for the -- for writing a press release is,</p> <p>3 they can only present data that was presented in the</p> <p>4 press -- they can only present data in the press</p> <p>5 release that is what was presented at the</p> <p>6 presentation to the public. This is consistent with</p> <p>7 that, and it is the 6-month data.</p> <p>8 BY MR. SAHAM:</p> <p>9 Q. Can you point to me where it says that</p> <p>10 the -- in this Exhibit 67, can you point to me to</p> <p>11 any spot in the press release where it says that the</p> <p>12 claim relating to the statistical significance of</p> <p>13 the nonaspirin subgroup for complicated ulcers is</p> <p>14 based on the 6-month data?</p> <p>15 A. I would go to Paragraph 1, line -- one,</p> <p>16 two, three, four, five -- six: "The findings</p> <p>17 presented at the American College of Physicians</p> <p>18 annual meeting," to me, says go to that.</p> <p>19 That was a focus of the 6-month data, and</p> <p>20 that's what this is referring to.</p> <p>21 Q. And do you know how a reader of this</p> <p>22 press release could attain the ACP presentation,</p> <p>23 either a video or slides of it?</p> <p>24 A. That, I can't speak to. I don't know how</p>	<p>160</p> <p>1 presentation?</p> <p>2 A. That's --</p> <p>3 MR. HOFF: Could you read back that question.</p> <p>4 (WHEREUPON, the record was read by</p> <p>5 the reporter.)</p> <p>6 BY THE WITNESS:</p> <p>7 A. The alternative definition was requested</p> <p>8 by the FDA, and there was -- the analyses were not</p> <p>9 completed. The statistical analyses were not</p> <p>10 conducted on that endpoint because we missed the</p> <p>11 primary comparison of Celebrex to NSAIDs for ulcer</p> <p>12 complications.</p> <p>13 In the statistical report, it says, if</p> <p>14 you miss on the -- that one, you can't make a claim</p> <p>15 on the FDA requested analysis.</p> <p>16 So that analysis was not done because, as</p> <p>17 acknowledged, we did not reach our primary endpoint</p> <p>18 for the primary analysis of Celebrex versus the</p> <p>19 NSAIDs compared together for ulcer complications.</p> <p>20 BY MR. SAHAM:</p> <p>21 Q. Do you recall that Diclofenac was</p> <p>22 numerically superior on the alternative definition</p> <p>23 of complicated ulcer as per the FDA's definition?</p> <p>24 A. I don't recall that.</p>





<p>161</p> <p>1 Q. Okay. Could you turn back to Exhibit 66,</p> <p>2 the final report, and specifically I'd like to turn</p> <p>3 your attention to Table 8.v on page 158.</p> <p>4 And this indicates that there were</p> <p>5 17 uncensored complicated ulcers in the Celecoxib</p> <p>6 treatment group using the FDA definition; is that</p> <p>7 correct, sir?</p> <p>8 A. So this table is for the entire study</p> <p>9 period which includes beyond six months, which is</p> <p>10 invalid data as determined by consensus of the</p> <p>11 external authors and the internal people.</p> <p>12 Q. Okay. But it --</p> <p>13 A. So in that context, yes, the number</p> <p>14 is 17.</p> <p>15 Q. Okay. And -- and the number for</p> <p>16 Diclofenac is five; is that correct?</p> <p>17 A. In this table, the number in the</p> <p>18 Diclofenac column is five.</p> <p>19 Q. And there are approximately double the</p> <p>20 number of people in the Celecoxib group?</p> <p>21 A. That's correct.</p> <p>22 Q. Okay. And the -- this table also</p> <p>23 calculates the crude incident rate, and for</p> <p>24 Celecoxib, that's --</p>	<p>163</p> <p>1 A. That's correct.</p> <p>2 Q. And there's 6-month data that's</p> <p>3 communicated regarding the combined endpoint, which</p> <p>4 wasn't even a primary endpoint, correct, of</p> <p>5 symptomatic ulcers and complicated ulcers together?</p> <p>6 That's communicated at six months, correct?</p> <p>7 A. The -- the -- the primary endpoint of the</p> <p>8 study was ulcer complications using the definition</p> <p>9 by the end- -- by Searle. The coprimary was used,</p> <p>10 the definition, by FDA.</p> <p>11 The incidence of symptomatic ulcers was</p> <p>12 predefined in the protocol to be analyzed. And it</p> <p>13 was appropriate, and it was clinically appropriate</p> <p>14 to do the combined endpoint analysis, which was</p> <p>15 presented for six months at the ACP meeting.</p> <p>16 Q. But the bias you're talking about before,</p> <p>17 that didn't in any way affect the -- the validity of</p> <p>18 6-month data for the coprimary endpoint on the FDA</p> <p>19 alternative definition; is that correct, sir?</p> <p>20 A. Repeat the question.</p> <p>21 Q. Your whole -- it's the informative</p> <p>22 censoring, the bias issue that you've been talking</p> <p>23 about of why you think the post 6-month data is</p> <p>24 invalid that you've talked about?</p>
<p>162</p> <p>1 A. Right.</p> <p>2 Q. -- .43; is that correct, sir?</p> <p>3 A. It is correct that the crude rate on this</p> <p>4 table for Celebrex is 0.43 percent.</p> <p>5 Q. And for Diclofenac, it's .25?</p> <p>6 A. It's correct that's what the number</p> <p>7 reads.</p> <p>8 Q. And that's about half of Celecoxib's</p> <p>9 crude incident rate?</p> <p>10 A. When you are looking at an analysis that</p> <p>11 includes an enormous amount of data that is invalid.</p> <p>12 So it's meaningless. The number --</p> <p>13 Q. It's the coprimary endpoint in the study,</p> <p>14 though, correct, sir?</p> <p>15 A. It was the co- -- it was predefined as a</p> <p>16 coprimary endpoint, but for all the reasons that</p> <p>17 have been described in the report and dis- -- and</p> <p>18 disclosed to the FDA, there was a bias in the study</p> <p>19 after six months. So the data beyond six months is</p> <p>20 not valid. The numbers are fundamentally</p> <p>21 uninterpretable.</p> <p>22 Q. But there's six months' data that was</p> <p>23 communicated regarding the other coprimary endpoint,</p> <p>24 correct?</p>	<p>164</p> <p>1 A. The post 6-month data is invalid.</p> <p>2 Q. That -- that whole bias --</p> <p>3 A. Right.</p> <p>4 Q. -- and validity analysis --</p> <p>5 A. Right.</p> <p>6 Q. -- wouldn't prevent you from analyzing</p> <p>7 this --</p> <p>8 A. Right.</p> <p>9 Q. -- coprimary endpoint at six months,</p> <p>10 correct? That wouldn't play into that; am I right</p> <p>11 about that, sir?</p> <p>12 A. It wouldn't have to.</p> <p>13 Q. But it wouldn't -- it wouldn't affect the</p> <p>14 six -- the validity of 6-month data on this</p> <p>15 coprimary endpoint?</p> <p>16 A. I haven't really thought about that in</p> <p>17 detail, so I -- I don't know. I'd have to think</p> <p>18 about that.</p> <p>19 Q. But you -- you would agree with me that</p> <p>20 this coprimary endpoint, which at least, according</p> <p>21 to this table, Diclofenac was numerically superior,</p> <p>22 that's not referenced in any way in the press</p> <p>23 release which is Plaintiffs' Exhibit 67?</p> <p>24 A. Ask the question again, please.</p>



<p>165</p> <p>1 Q. This -- this data about the -- any data</p> <p>2 about the coprimary endpoint, none of that is</p> <p>3 referenced in Exhibit 67; am I right about that?</p> <p>4 A. It's --</p> <p>5 Q. Or am I somehow reading Exhibit 67 --</p> <p>6 A. It's not --</p> <p>7 Q. -- inaccurately?</p> <p>8 A. It's not represented in Exhibit 67, which</p> <p>9 is the press release, because it was not presented</p> <p>10 by Dr. Silverstein at the American College of</p> <p>11 Physicians, and it couldn't be by FDA rules.</p> <p>12 Q. So Dr. Silverstein was prevented from</p> <p>13 talking about the coprimary endpoint at the ACP?</p> <p>14 A. Dr. Silverstein was not prevented to do</p> <p>15 anything.</p> <p>16 Q. He could have talked about the coprimary</p> <p>17 endpoint?</p> <p>18 A. If people -- he could have.</p> <p>19 Q. And he could have talked about the entire</p> <p>20 study data? There was nothing preventing him from</p> <p>21 doing it?</p> <p>22 A. The data that Dr. Silverstein presented</p> <p>23 was the data that was considered the most valid data</p> <p>24 for the primary analysis of this study --</p>	<p>167</p> <p>1 Were you involved in the decision to use</p> <p>2 the 6-month data instead of the entire study data?</p> <p>3 A. I was involved in the de- -- in the</p> <p>4 decision-making as one of the scientists</p> <p>5 participating in analysis review that the 6-month</p> <p>6 analysis was valid, and beyond that, it was not</p> <p>7 valid.</p> <p>8 As part of that, I was part of -- I</p> <p>9 endorsed the presentation of the most valid data or</p> <p>10 the valid data from this study when it was publicly</p> <p>11 disclosed.</p> <p>12 Q. And Dr. Needleman was part of that</p> <p>13 process, as well?</p> <p>14 A. We worked in a collaborative effort. Our</p> <p>15 decisions were made with getting scientists and</p> <p>16 clinicians to look at data together and give their</p> <p>17 insights into what they think is the results of the</p> <p>18 trial, interpretation of analyses and hence, what is</p> <p>19 the most valid data.</p> <p>20 Dr. Needleman, in that sense,</p> <p>21 participated in all of those activities.</p> <p>22 Q. Okay. So in addition to yourself and</p> <p>23 Dr. Needleman, who else that was employed by</p> <p>24 Pharmacia or Searle participated in those</p>
<p>166</p> <p>1 Q. And who --</p> <p>2 A. -- including -- can I finish, please?</p> <p>3 Q. Sure. Sorry about that.</p> <p>4 A. -- including other appropriate analyses</p> <p>5 to give physicians an understanding of how Celebrex</p> <p>6 compared to the combined NSAIDs in terms of GI</p> <p>7 toxicity. That was the overriding comparison that</p> <p>8 people were interested when we designed the study,</p> <p>9 when the study was conducted and at the end. So</p> <p>10 that was the focus of the presentation.</p> <p>11 There are other analyses in -- in a</p> <p>12 trial, as there always are, that you -- that you</p> <p>13 just make the clinical judgment that that's not what</p> <p>14 we're going to present here.</p> <p>15 Q. You were involved in the decision to just</p> <p>16 publicize the 6-month data; is that correct?</p> <p>17 A. When you say "publicize," explicitly what</p> <p>18 are you talking about?</p> <p>19 Q. I'm talking about presenting it at the</p> <p>20 ACP and publicizing it in this press release. And</p> <p>21 we're going to get to the JAMA article, but that's</p> <p>22 what I'm talking about, putting it in press</p> <p>23 releases, putting -- presenting it at ACP and</p> <p>24 presenting it in the JAMA article.</p>	<p>168</p> <p>1 discussions which resulted in the decision to</p> <p>2 publicize, as I've described it, the 6-month data as</p> <p>3 opposed to the entire study data?</p> <p>4 A. So I -- I want to break that down. One</p> <p>5 thing you said is, who was involved in, I think you</p> <p>6 asked me, reviewing the data to decide what was the</p> <p>7 most valid. And then the second part was, and who</p> <p>8 decided what to publish, so I'd like to handle them</p> <p>9 separately.</p> <p>10 Q. Well -- well, let's just break it down so</p> <p>11 it's clear in the record what we're talking about.</p> <p>12 A. Okay.</p> <p>13 Q. Who -- who made the decision -- let's</p> <p>14 just stick with you say -- and for the purposes of</p> <p>15 this question, you say the 6-month data was valid,</p> <p>16 the rest of the data was invalid.</p> <p>17 Who -- and -- and I want to exclude</p> <p>18 external authors for a second. We can get to them</p> <p>19 in a second.</p> <p>20 Who, that was employed by one of these</p> <p>21 companies, either Pharmacia, Pfizer, Searle -- I</p> <p>22 believe you testified -- and just want to get this</p> <p>23 in little bitty steps -- that yourself and</p> <p>24 Dr. Needleman were involved in that process of</p>



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<p>169</p> <p>1 talking about it and making the decision; am I</p> <p>2 correct about that, sir?</p> <p>3 MR. HOFF: Whoa, whoa.</p> <p>4 BY THE WITNESS:</p> <p>5 A. I didn't --</p> <p>6 MR. HOFF: Wait, wait, wait a second. I'm</p> <p>7 going to object to the form of the question.</p> <p>8 MR. SAHAM: I'll ask a different question.</p> <p>9 I'll withdraw the question --</p> <p>10 MR. HOFF: Please.</p> <p>11 MR. SAHAM: -- if you're objecting to it.</p> <p>12 BY MR. SAHAM:</p> <p>13 Q. I -- I want to break this down so we can</p> <p>14 do this in little steps --</p> <p>15 A. Sure.</p> <p>16 Q. -- and -- and hopefully get a question</p> <p>17 that you can answer yes or no. And then you're</p> <p>18 going to get a chance to give your explanation, but</p> <p>19 I just want my simple, straightforward questions so</p> <p>20 the record's clear: Is it correct that you</p> <p>21 personally, you know, Steven George Geis,</p> <p>22 participated in the decision or the discussions</p> <p>23 regarding whether to use the 6-month data or the</p> <p>24 12-month data?</p>	<p>171</p> <p>1 opportunity to agree or disagree about the validity</p> <p>2 of the six months. I never remember anyone saying,</p> <p>3 I disagree.</p> <p>4 Q. Is it correct --</p> <p>5 A. So any- -- so anybody who was in the</p> <p>6 room, I would say, by consensus, agreed the six</p> <p>7 months was the valid data for the GI complications</p> <p>8 and the symptomatic ulcers.</p> <p>9 Q. Is it correct that Mr. Hassan, then,</p> <p>10 agreed that the 6-month data was appropriately</p> <p>11 the -- the valid data as opposed to the entire study</p> <p>12 data?</p> <p>13 A. I would not interpret that that way.</p> <p>14 Because I wouldn't interpret that presentation in</p> <p>15 the same light as presenting data to Phil Needleman</p> <p>16 and other scientists who are intimately involved</p> <p>17 with this study for two years and compare that to</p> <p>18 Mr. Hassan who's seeing it for the first time --</p> <p>19 Q. But -- but --</p> <p>20 A. -- Mr. Hassan, excuse me.</p> <p>21 Q. And Mr. Hassan, then, was aware that</p> <p>22 there was approximately 12 or 13 months of data and</p> <p>23 that only the valid 6-month data was going to be</p> <p>24 publicly communicated; is that correct, sir?</p>
<p>170</p> <p>1 A. I participated in discussions that looked</p> <p>2 at the data that came to the conclusion the 6-month</p> <p>3 data was the valid data. In that sense, yes.</p> <p>4 Q. And Dr. Needleman participated in those</p> <p>5 discussions?</p> <p>6 A. Dr. Needleman participated in the</p> <p>7 discussions that looked at the data and came to the</p> <p>8 conclusion that the 6-month data for ulcer</p> <p>9 complications and the -- and the GI endpoints was</p> <p>10 the valid data.</p> <p>11 Q. Who else at Pharmacia participated in</p> <p>12 those discussions that were senior to you?</p> <p>13 A. So if we could hearken back to some of</p> <p>14 the discussions we had earlier about presentations</p> <p>15 that went on between the day the database was</p> <p>16 closed, the blind, broken, and the analysis brought</p> <p>17 forward, in all of those presentations, how many</p> <p>18 there may have been, the intent is not -- the intent</p> <p>19 is for discussion, input and conversation and</p> <p>20 hopefully coming to a conclusion of what is the most</p> <p>21 valid data.</p> <p>22 In any one of those presentations, any --</p> <p>23 and your question is anybody higher than me at</p> <p>24 Searle, if they were in the room, they had the</p>	<p>172</p> <p>1 A. In the presentation that --</p> <p>2 MR. HOFF: Objection to form.</p> <p>3 BY THE WITNESS:</p> <p>4 A. So I gave a presentation in PEPAC. I</p> <p>5 think we have, by the documents, assessed or</p> <p>6 determined that it was in early April where Fred</p> <p>7 Hassan was present and I presented the data, which</p> <p>8 included the data beyond the six months, the</p> <p>9 explanation for why we thought the 6-month data was</p> <p>10 the valid data. He was there for that presentation.</p> <p>11 BY MR. SAHAM:</p> <p>12 Q. And -- and Ms. Cox was there, as well?</p> <p>13 A. Ms. Cox was at that presentation.</p> <p>14 Q. And Dr. Ando was there, as well?</p> <p>15 A. He was.</p> <p>16 Q. Okay. And any of those individuals could</p> <p>17 have certainly spoken up and said, no, you -- you</p> <p>18 should publish the entire data and an explanation as</p> <p>19 to why six months is better --</p> <p>20 MR. HOFF: Objection.</p> <p>21 BY MR. SAHAM:</p> <p>22 Q. -- or more valid?</p> <p>23 MR. HOFF: Objection to form.</p> <p>24 BY THE WITNESS:</p>



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<p>173</p> <p>1 A. I mean, it could or couldn't. I don't</p> <p>2 know. What -- could or couldn't at a meeting? I</p> <p>3 don't know what they could or couldn't have said.</p> <p>4 BY MR. SAHAM:</p> <p>5 Q. Let me -- let me ask it this way --</p> <p>6 A. These were open meetings for discussions.</p> <p>7 Q. Okay.</p> <p>8 A. I mean, I don't know what was going on in</p> <p>9 their heads. You're asking me to guess what was</p> <p>10 Fred Hassan thinking.</p> <p>11 Q. Let -- let's just break this down.</p> <p>12 You made a presentation to Hassan, Cox</p> <p>13 and Ando that made them aware there was data beyond</p> <p>14 six months; is that correct?</p> <p>15 A. Yes, in -- in early April.</p> <p>16 Q. And you also made them aware that in your</p> <p>17 opinion and Dr. Needleman's opinion, that the</p> <p>18 6-month data was more valid due to the informative</p> <p>19 censoring issue?</p> <p>20 A. I -- I would like to correct you on that.</p> <p>21 You're making it sound like it was just Needleman</p> <p>22 and my opinion. They were made aware that this data</p> <p>23 had been presented in -- in front of multiple</p> <p>24 scientists internally. And I believe, after -- the</p>	<p>175</p> <p>1 Q. Okay. And do you know what happened to</p> <p>2 those PowerPoint slides that you used?</p> <p>3 A. No --</p> <p>4 Q. Okay.</p> <p>5 A. -- I do not.</p> <p>6 Q. Have you looked for them?</p> <p>7 A. I have. And I can't find a set that has</p> <p>8 me convinced I know which ones they were.</p> <p>9 MR. SAHAM: It's probably a convenient breaking</p> <p>10 time for lunch if you guys are hungry.</p> <p>11 MR. HOFF: It's a convenient time to break if</p> <p>12 you want.</p> <p>13 MR. SAHAM: Yeah, let's take lunch.</p> <p>14 THE VIDEOGRAPHER: Going off the video record</p> <p>15 at 12:52 p.m.</p> <p>16 (WHEREUPON, the deposition was</p> <p>17 recessed until 1:30 p.m.,</p> <p>18 this date.)</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
<p>174</p> <p>1 presentation to Mr. Hassan and Ms. Cox was after we</p> <p>2 had been in front of the -- the external authors.</p> <p>3 So you had a wide spectrum of scientists</p> <p>4 and physicians who all had agreed that this 6-months</p> <p>5 was the most valid, including Dr. Needleman and</p> <p>6 myself and Mr. Hassan and Ms. Cox heard that that is</p> <p>7 what had transpired.</p> <p>8 Q. Okay. So they were made aware of the</p> <p>9 explanation as to why the 6-month data was more</p> <p>10 valid than the entire study data?</p> <p>11 A. I explained the reasons why, yes, in the</p> <p>12 presentation, as to why we thought the six months</p> <p>13 was the valid data.</p> <p>14 Q. And that -- just so the record's clear,</p> <p>15 that presentation was made to Mr. Hassan, Ms. Cox</p> <p>16 and Dr. Ando, as well as others?</p> <p>17 A. Correct. This is the presentation I'm</p> <p>18 referring to in the early part of April where</p> <p>19 multiple people were present, and I do remember</p> <p>20 those folks being there.</p> <p>21 Q. And you made a PowerPoint presentation at</p> <p>22 that meeting?</p> <p>23 A. It included PowerPoint slides and the use</p> <p>24 of a flip chart.</p>	<p>176</p> <p>1 UNITED STATES DISTRICT COURT</p> <p>2 DISTRICT OF NEW JERSEY</p> <p>3</p> <p>4 ALASKA ELECTRICAL PENSION )</p> <p>5 FUND, et al., On Behalf of )</p> <p>6 Themselves and All Others ) No. 03-1519</p> <p>7 Similarly Situated, ) (AET)</p> <p>8 Plaintiffs, )</p> <p>9 vs. )</p> <p>10 PHARMACIA CORPORATION, et al., )</p> <p>11 Defendants. )</p> <p>12</p> <p>13 12/10/2010</p> <p>14 1:34 p.m.</p> <p>15</p> <p>16 The deposition of STEVEN GEIS resumed</p> <p>17 pursuant to recess at Suite 900, One South Dearborn</p> <p>18 Street, Chicago, Illinois.</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>



<p>177</p> <p>1 PRESENT:</p> <p>2</p> <p>3 ROBBINS GELLER RUDMAN &amp; DOWD, LLP,</p> <p>4 (665 West Broadway, Suite 1900,</p> <p>5 San Diego, California 92101,</p> <p>6 619-231-1058), by:</p> <p>7 MR. SCOTT H. SAHAM,</p> <p>8 MR. LUCAS F. OLTS,</p> <p>9 -and-</p> <p>10 SCOTT &amp; SCOTT LLP,</p> <p>11 (707 Broadway, Suite 1000,</p> <p>12 San Diego, California 92101,</p> <p>13 619-233-4565), by:</p> <p>14 MR. MATTHEW MONTGOMERY,</p> <p>15 appeared on behalf of the Plaintiffs;</p> <p>16</p> <p>17 CADWALADER, WICKERSHAM &amp; TAFT LLP,</p> <p>18 (One World Financial Center,</p> <p>19 New York, New York 10281,</p> <p>20 212-504-6474), by:</p> <p>21 MR. JONATHAN M. HOFF,</p> <p>22 MR. JOSHUA R. WEISS,</p> <p>23 appeared on behalf of the Defendants.</p> <p>24</p>	<p>179</p> <p>1 THE VIDEOGRAPHER: Going back on the video</p> <p>2 record at 1:34 p.m.</p> <p>3 This is the beginning of Tape No. 4.</p> <p>4 STEVEN GEIS,</p> <p>5 called as a witness herein, having been previously</p> <p>6 duly sworn and having testified, was examined and</p> <p>7 testified further as follows:</p> <p>8 EXAMINATION (Resumed)</p> <p>9 BY MR. SAHAM:</p> <p>10 Q. Dr. Geis, can you look at Exhibit 250,</p> <p>11 specifically slide 43.</p> <p>12 MR. SAHAM: Like this one, John.</p> <p>13 BY MR. SAHAM:</p> <p>14 Q. And could you just tell me what's being</p> <p>15 communicated in that slide?</p> <p>16 A. So I just want to make sure I'm on the</p> <p>17 right 40 -- 43. It's entitled Complication Rates</p> <p>18 (All) Over 12 Months?</p> <p>19 Q. Correct.</p> <p>20 A. And it's also entitled a draft?</p> <p>21 Q. Correct.</p> <p>22 A. Okay. This -- this appears to be a draft</p> <p>23 slide that looks at crude rates calculated at</p> <p>24 3 months, 6 months and then at 12 months for</p>
<p>178</p> <p>1 ALSO PRESENT:</p> <p>2</p> <p>3 MR. KEVIN DAILEY, Legal Videographer,</p> <p>4 Esquire Deposition Solutions.</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23 REPORTED BY: NICOLE M. SCOLA, CSR, RPR,</p> <p>24 C.S.R. Certificate No. 84-4524.</p>	<p>180</p> <p>1 Celecoxib versus the combined NSAIDs together.</p> <p>2 Q. And when you say "crude rates," that's</p> <p>3 the crude rate of ulcer complication?</p> <p>4 A. It appears to me from the title that it</p> <p>5 says complication rates. I -- I'm assuming that</p> <p>6 it -- they're referring to the ulcer complications.</p> <p>7 Q. And this indicates that Celebrex has more</p> <p>8 of an advantage at 6 months than at 12 months, at</p> <p>9 least per the slide; is that correct?</p> <p>10 A. Well, I mean -- what was your question</p> <p>11 again?</p> <p>12 Q. Well, my question is, the difference</p> <p>13 between Celecoxib and the NSAIDs, at least according</p> <p>14 to this graph, is greater at 6 months than it is at</p> <p>15 12 months; is that a correct statement?</p> <p>16 A. If you -- if you're only looking at these</p> <p>17 data on this slide, but you can't look just at this</p> <p>18 data because this includes the data beyond six</p> <p>19 months. We -- beyond six months, we believe is</p> <p>20 invalid, and therefore, any of the comparisons, any</p> <p>21 of the numbers is highly in question.</p> <p>22 So I look at it and say, beyond six</p> <p>23 months, frankly, I don't even try to interpret it.</p> <p>24 It makes no sense to me beyond six months.</p>



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<p>181</p> <p>1 Q. Right. I -- I understand that and I</p> <p>2 understand that you believe or you've testified --</p> <p>3 you know, I don't know what you believe, but I</p> <p>4 understand that you've testified that you don't</p> <p>5 think that data after six months is -- is valid, but</p> <p>6 at least according to this table -- well,</p> <p>7 irrespective of its validity -- and we can debate</p> <p>8 that -- at least on the complicated ulcer rate, that</p> <p>9 it's -- Celebrex looks better compared to the two</p> <p>10 NSAIDs at 6 months than it does at 12, regardless of</p> <p>11 whether or not the data's valid; is that correct,</p> <p>12 sir?</p> <p>13 A. So based on -- somebody put this</p> <p>14 together. I don't even know -- even though I might</p> <p>15 think it's in- -- I believe it's invalid after six</p> <p>16 months, I don't even know if it's correct.</p> <p>17 So having said that, the line is, the</p> <p>18 difference at 6 months looks wider than the</p> <p>19 difference at 12 months. But in that context, I</p> <p>20 don't know if it's accurate. It's identified as a</p> <p>21 draft, and beyond six months, it's invalid data.</p> <p>22 Q. Okay. Well, if we look back at</p> <p>23 Exhibit 66, the signed final study report, pages 6</p> <p>24 and 7, the Tables 1 through 4, is it accurate that</p>	<p>183</p> <p>1 which is the first column for Celecoxib anyway, and</p> <p>2 then the second column for Diclofenac and the third</p> <p>3 column for Ibuprofen --</p> <p>4 A. So --</p> <p>5 Q. -- do you see that?</p> <p>6 A. -- precisely what is the question?</p> <p>7 Q. Well, I haven't asked the question.</p> <p>8 A. Okay. Yes.</p> <p>9 Q. I just want to make sure you're looking</p> <p>10 at that.</p> <p>11 A. I'm looking at the raw numbers.</p> <p>12 Q. So -- so basically, there were, for the</p> <p>13 entire study period with respect to Celecoxib, six</p> <p>14 of the seven uncensored CSUGIEs occurred after six</p> <p>15 months; is that correct?</p> <p>16 A. So you're comparing 11 in Table 1 versus</p> <p>17 17 in Table 2, and you're asking me, is 17 greater</p> <p>18 than 11? Yes.</p> <p>19 Q. No. I'm just asking you, six of the</p> <p>20 seven complicated ulcers that occurred that were</p> <p>21 uncensored that occurred in the Celecoxib treatment</p> <p>22 group occurred after six months; is that correct,</p> <p>23 sir?</p> <p>24 A. I still don't follow you. Where are you</p>
<p>182</p> <p>1 virtually all of the P Value comparisons, whether</p> <p>2 it's for Celebrex versus Diclofenac, Celebrex versus</p> <p>3 Ibuprofen or both, is it a fair characterization</p> <p>4 that virtually every one of the various P Value</p> <p>5 comparisons increase for the entire study as</p> <p>6 compared to the six months?</p> <p>7 A. So let me get this straight. Comparing</p> <p>8 Table 1, which is six months, versus Table 2, which</p> <p>9 is entire study, you're asking me if the P Value,</p> <p>10 these isolated numbers, are -- are higher in the</p> <p>11 entire study period versus the six months?</p> <p>12 Q. Correct.</p> <p>13 A. No, that's not true.</p> <p>14 Q. Which one is not higher?</p> <p>15 A. Oh, I apologize, I -- I read this one</p> <p>16 wrong.</p> <p>17 So looking at Table 1 and Table 2, the</p> <p>18 table that includes all the invalid data that we</p> <p>19 don't think is interpretable is associated with</p> <p>20 P Values higher than the table of the data that we</p> <p>21 think is valid and useful for interpretation.</p> <p>22 Q. And also, when you look at this, just the</p> <p>23 raw numbers, the uncensored CSUGIEs, which is the</p> <p>24 first column or the uncensored ulcer complications,</p>	<p>184</p> <p>1 get -- coming up with the number seven? I see --</p> <p>2 Q. Let me ask it differently.</p> <p>3 Out of the 17 -- and I apologize</p> <p>4 greatly -- out of the 17 Celecoxib uncensored</p> <p>5 complicated ulcers that occurred in the CLASS study,</p> <p>6 six of those occurred after six months; is that</p> <p>7 correct, sir?</p> <p>8 A. Based on this table, the 17, yes. The</p> <p>9 seven of the -- there were 11 that occurred in the</p> <p>10 first six months, and there were 17 occurred in</p> <p>11 the -- in the second six, but over the entire</p> <p>12 period. So there were six additional ones that</p> <p>13 occurred after six months --</p> <p>14 Q. And --</p> <p>15 A. -- in the invalid part of the study.</p> <p>16 Q. Right. And with respect to Diclofenac,</p> <p>17 that's only -- only one occurred after six months;</p> <p>18 is that correct?</p> <p>19 A. Again, yes. In the valid part of the</p> <p>20 study, it was nine. In the invalid, there was an</p> <p>21 additional one.</p> <p>22 Q. And with respect to Ibuprofen, no</p> <p>23 additional complicated ulcers occurred after six</p> <p>24 months?</p>



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<p style="text-align: center;">185</p> <p>1 A. Right, which is the invalid part of the 2 study. 3 Q. So I know this is just plain third-grade 4 math, but -- 5 A. Sure. 6 Q. -- six of the seven complicated ulcers 7 that occurred after six months were in the Celecoxib 8 treatment group; is that correct? 9 A. Yes. In the invalid part of the study, 10 agreed. 11 Q. Okay. But you would agree after six 12 months -- 13 A. Which is the invalid part of the study. 14 Q. -- yeah -- six of those seven complicated 15 ulcers were in the Celecoxib treatment group; is 16 that correct, sir? 17 A. Six of the seven? No, there were six. 18 Q. No. There were seven total because there 19 was also one in the Diclofenac group that occurred 20 after six months. 21 A. Oh, I'm sorry. 22 Q. So there were seven after six months, and 23 six of those seven were in the Celecoxib group, 24 correct?</p>	<p style="text-align: center;">187</p> <p>1 that's -- that's why we believe the second part of 2 this study was invalid. 3 Q. You -- you never scientifically proved 4 that that's what was happening, that there was a 5 bias that led to the -- or strike that question. 6 You -- you never did any scientific work 7 to determine whether the informative censoring or 8 bias claim was actually what was occurring? That 9 was a theory, correct? 10 A. That's incorrect. 11 Q. What did you do? 12 A. So let's go back to -- you -- you're 13 using some terms here that I think we need to 14 clarify so we don't get caught. 15 Q. Well, let me withdraw the question. I'm 16 going to withdraw the question. 17 My -- my question to you is, was it 18 scientifically proven that the bias that you've 19 described was at work? Was that proven 20 scientifically? 21 A. The bias that I am describing is that 22 there is a differential dropout rate in the two 23 treatment groups in patients most likely to develop 24 an ulcer complication. And there was a higher</p>
<p style="text-align: center;">186</p> <p>1 A. Yes. In the invalid part -- in the 2 invalid part of the study, there were seven 3 additional uncensored clinically significant ulcer 4 complications, of which six were in the Celebrex 5 group and one in the Diclofenac. 6 Q. And mathematically, that caused the 7 P Values to increase from six months to the entire 8 study period, correct? 9 A. Mathematically? Math -- ask the question 10 again. 11 Q. Statistically, because six of the seven 12 complicated ulcers that occurred after six months 13 were in the Celecoxib treatment group, it made those 14 P Values -- when you look, six compared to the 15 entire study, it made them increase; isn't that 16 right? 17 A. So if we're doing math, I don't know what 18 the math is. But the reason that the P Values 19 increased is because you had an imbalance in the 20 dropout rates of patients -- you had differential 21 dropout of patients most likely to develop an ulcer 22 complication in the NSAID treatment groups. 23 Now, that may turn into a mathematical 24 equation that you say increases P Values, but</p>	<p style="text-align: center;">188</p> <p>1 dropout rate of people who had symptomatic ulcers in 2 the NSAID group versus the Celebrex group as the 3 study progressed. That is -- there's numbers. You 4 can look at the tables. You can look at the figures 5 and show that. 6 Symptomatic ulcers are -- have been 7 historically correlated to ulcer complications. 8 Recently, FDA had an advisory committee on 9 November 4th where this issue was discussed among 10 experts in the field in front of an advisory 11 committee, and FDA conferred with representatives 12 from the industry that ulcers are surrogates for 13 ulcer complications. 14 So if you have more people who are 15 dropping out in the NSAID group due to symptomatic 16 ulcers than ulcer complications, that creates a 17 bias. I would submit that that is scientific and -- 18 and methodological and that's scientific evidence. 19 That is data that says, yes, there was this 20 differential dropout that made the -- the data after 21 six months invalid. 22 Q. So -- so I understand it, are you saying 23 it's the occurrence of symptomatic ulcers and the 24 withdrawal rate based on the occurrence of</p>



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<p>189</p> <p>1 symptomatic ulcers that created the bias; is that</p> <p>2 correct, sir?</p> <p>3 A. What I'm saying is that -- so what I'm</p> <p>4 saying is that the withdrawal due to symptomatic</p> <p>5 ulcers, to me, is the most rigorous explanation.</p> <p>6 But there is also a component of, we know that</p> <p>7 patients who have GI symptoms, there is a</p> <p>8 correlation between GI symptoms and an ulcer</p> <p>9 complication. And there was a differential dropout</p> <p>10 rate due to GI symptoms in the NSAIDs group versus</p> <p>11 the Celecoxib group.</p> <p>12 Q. Are you aware of --</p> <p>13 A. So the differential dropout rate due to</p> <p>14 GI symptoms also contributed to the bias after six</p> <p>15 months, which invalidated the post-6-month data.</p> <p>16 Q. Are you aware that there's scientific</p> <p>17 literature out there that says that there isn't a</p> <p>18 correlation between symptoms and a bleed?</p> <p>19 A. I have -- I mean, over the years, I've --</p> <p>20 I've studied this quite a bit, and there are people</p> <p>21 who do say that.</p> <p>22 However, I disagree, and I think that the</p> <p>23 history of medicine would disagree because</p> <p>24 physicians believe and see in their practices that</p>	<p>191</p> <p>1 I'd ask you if you recognize this</p> <p>2 document?</p> <p>3 And I will certainly refer you to the</p> <p>4 specific sections that I want to ask you about.</p> <p>5 I'd ask you if you recognize this</p> <p>6 document?</p> <p>7 A. Yes, I do.</p> <p>8 Q. And what is it?</p> <p>9 A. It is the JAMA publication of the CLASS</p> <p>10 results from September of 2000.</p> <p>11 Q. And you are an author of this article?</p> <p>12 A. Correct.</p> <p>13 Q. And specifically, my first question is,</p> <p>14 there's no explanation in this article, Exhibit 3,</p> <p>15 as to the bias being the reason for utilizing six</p> <p>16 months of data; is that correct, sir?</p> <p>17 A. I haven't read this in a while, but I --</p> <p>18 so I would say I don't know unless I read it word</p> <p>19 for word again.</p> <p>20 Q. So you -- well, I mean, the -- the</p> <p>21 document says -- it says what it says.</p> <p>22 I mean, do you -- do you recall there</p> <p>23 being an explanation in here of the -- the bias</p> <p>24 being the -- that you've described earlier today,</p>
<p>190</p> <p>1 the more severe symptoms you have, the more likely</p> <p>2 you are that you're going to have a problem in your</p> <p>3 GI tract.</p> <p>4 Q. Would you concede that reasonable minds</p> <p>5 could disagree on that point whether symptoms</p> <p>6 correlate with a bleed?</p> <p>7 A. Not anymore. Maybe years ago, but not</p> <p>8 anymore because the data has come out in mass and</p> <p>9 repeatedly in the past ten years, which has</p> <p>10 basically confirmed this.</p> <p>11 Q. At -- at the time of the CLASS trial and</p> <p>12 the publication of the JAMA article in September of</p> <p>13 2000, would you say that reasonable minds could have</p> <p>14 disagreed as to whether symptoms correlated with the</p> <p>15 bleed?</p> <p>16 A. I can't -- I mean, who -- I would highly</p> <p>17 question whether they were -- were reasonable minds</p> <p>18 if they disagree, because the data was so</p> <p>19 compelling. And there always has been a correlation</p> <p>20 between GI symptoms and symptomatic ulcers and with</p> <p>21 ulcer complications.</p> <p>22 Q. Okay. I want to show you what's</p> <p>23 previously been marked as Plaintiffs' Wolfe</p> <p>24 Exhibit 3.</p>	<p>192</p> <p>1 being the reason for utilizing the 6-month data?</p> <p>2 A. I don't recall that it was in here.</p> <p>3 Q. Okay. And do you recall that you only</p> <p>4 submitted -- you and the authors only submitted the</p> <p>5 6-month data to JAMA?</p> <p>6 A. We submitted, as we do with any</p> <p>7 publication, the data that we think is the valid</p> <p>8 data from a clinical trial. In this case, it was</p> <p>9 the 6-month data.</p> <p>10 Q. Okay. But it's your recollection, then,</p> <p>11 you submitted the 6-month data only to the JAMA</p> <p>12 editorial board?</p> <p>13 A. Again, we -- you know, I think the</p> <p>14 context that I think is appropriate is, we submitted</p> <p>15 the valid data, as we always do, for the results of</p> <p>16 the clinical trial.</p> <p>17 Q. Okay. But the valid data in your mind --</p> <p>18 the data -- there was no data beyond six months that</p> <p>19 was submitted to JAMA with respect to these GI</p> <p>20 endpoints that are discussed in Exhibit 3; is that</p> <p>21 correct?</p> <p>22 A. Correct.</p> <p>23 Q. Okay. And I want to show you what I'm</p> <p>24 marking here as Plaintiffs' Exhibit 257.</p>



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<p>193</p> <p>1 (WHEREUPON, a certain document was</p> <p>2 marked Plaintiffs' Deposition</p> <p>3 Exhibit No. 257, for identification,</p> <p>4 as of 12/10/2010.)</p> <p>5 BY MR. SAHAM:</p> <p>6 Q. And I just quickly -- I represent to you</p> <p>7 that this is the -- at least a portion of the</p> <p>8 deposition transcript that was produced in this case</p> <p>9 where you testified in the PI case, the In Re:</p> <p>10 Bextra and Celebrex litigation.</p> <p>11 Do you recall having testified in -- in</p> <p>12 that case on or about January 24, 2008?</p> <p>13 A. I testified -- I gave a deposition at</p> <p>14 some point that may have been around this time. I</p> <p>15 don't know how you described it. I don't -- I don't</p> <p>16 recognize that as the -- the case that you're</p> <p>17 speaking of.</p> <p>18 Q. But do you recall giving a -- a -- a</p> <p>19 videotaped deposition in -- in -- at least -- the</p> <p>20 title of this deposition is Steven Geis, and it</p> <p>21 says, In Re: Bextra and Celebrex Marketing Sales</p> <p>22 Practice and Product Liability Litigation.</p> <p>23 A. I don't recognize the title, but I know I</p> <p>24 gave a deposition.</p>	<p>195</p> <p>1 given that only the 6-month data was even submitted</p> <p>2 to JAMA, would that be consistent, now that you look</p> <p>3 at this article, that there's no reference in here</p> <p>4 to an explanation as to why only the 6-month --</p> <p>5 well, that's a bad question.</p> <p>6 I mean, I guess -- I think what we have</p> <p>7 to do, sir, if you cannot answer the question</p> <p>8 without looking at this document, I need an answer</p> <p>9 to that question whether or not there's an</p> <p>10 explanation in here as to why the 6-month data was</p> <p>11 being utilized.</p> <p>12 MR. HOFF: So --</p> <p>13 MR. SAHAM: My question is simply --</p> <p>14 MR. HOFF: -- you want -- you want him to</p> <p>15 answer that question?</p> <p>16 BY MR. SAHAM:</p> <p>17 Q. Yeah. My -- my question, sir -- and you</p> <p>18 can take as much time as you need. My question to</p> <p>19 you is, there was no explanation in Exhibit 3</p> <p>20 explaining that the reason the 6-month data was</p> <p>21 utilized was because of this bias you've described,</p> <p>22 and my question to you; is that correct, sir?</p> <p>23 A. Okay. I'd have to take a look through</p> <p>24 this to make sure that there isn't any reference to</p>
<p>194</p> <p>1 Q. Okay. And I -- I turn your attention to</p> <p>2 page 446.</p> <p>3 And you were asked the question: "And</p> <p>4 only six months of that data was given to JAMA for</p> <p>5 the publication, correct?"</p> <p>6 And you answered: "Well, the six months</p> <p>7 was considered the valid data which was given to</p> <p>8 JAMA for publication."</p> <p>9 You were then asked: "And who made that</p> <p>10 decision to only provide six months of data to</p> <p>11 JAMA?"</p> <p>12 "Answer: So the decision to provide the</p> <p>13 valid data to JAMA, which happened to be six months,</p> <p>14 was in conjunction with the external authors of the</p> <p>15 manuscript and the internal people at Searle."</p> <p>16 Do you see that?</p> <p>17 A. Correct.</p> <p>18 Q. And you believe that's truthful and</p> <p>19 accurate testimony?</p> <p>20 A. Yes.</p> <p>21 Q. Turning your attention back to Wolfe</p> <p>22 Exhibit 3, the JAMA article in which you're an</p> <p>23 author, the fact that only the six months -- and I</p> <p>24 know you like to call it the -- the valid data --</p>	<p>196</p> <p>1 that.</p> <p>2 Q. And -- and I guess the question -- and</p> <p>3 I'd accept that as an answer -- is your</p> <p>4 understanding, as we sit here today, that there was</p> <p>5 not a reference and you're just not certain?</p> <p>6 A. I -- I -- I be- -- I -- as I recall,</p> <p>7 there was no reference to that.</p> <p>8 Q. Okay. I'll -- I'll accept that.</p> <p>9 A. Let me say it again to be complete:</p> <p>10 There was no reference explaining why the 6-month</p> <p>11 data was the valid data.</p> <p>12 Q. And is it also accurate that</p> <p>13 Dr. Silverstein, who's the first author on this</p> <p>14 article, told you that he wanted to include such an</p> <p>15 explanation?</p> <p>16 A. That Dr. Goldstein told me --</p> <p>17 MR. HOFF: Silverstein.</p> <p>18 BY THE WITNESS:</p> <p>19 A. Dr. Silverstein told me he wanted an</p> <p>20 explanation as to why the 6-month data was being</p> <p>21 presented?</p> <p>22 BY MR. SAHAM:</p> <p>23 Q. Correct.</p> <p>24 A. Is that the question?</p>



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<p style="text-align: center;">197</p> <p>1 Q. That's the question.</p> <p>2 A. I don't recall that conversation.</p> <p>3 Q. Now, looking at Exhibit 3, is it also</p> <p>4 accurate that there's no reference in here to the</p> <p>5 fact that there was not a statistically significant</p> <p>6 difference with Diclofenac on any of those GI</p> <p>7 endpoints we've been discussing today?</p> <p>8 A. The manuscript described the results of</p> <p>9 the overall objective of the study to compare</p> <p>10 Celebrex versus the NSAIDs combined. For the</p> <p>11 primary endpoint of ulcer complications, clearly we</p> <p>12 state we did not reach statistical significance in</p> <p>13 terms of ulcer complications in comparing Celebrex</p> <p>14 versus the NSAID group together.</p> <p>15 Q. Can you -- can you --</p> <p>16 A. I'd --</p> <p>17 Q. Oh, sorry.</p> <p>18 A. -- like to finish my --</p> <p>19 Q. Sorry.</p> <p>20 A. -- statement.</p> <p>21 Per the statistical analysis plan, if</p> <p>22 you -- so -- so the first big picture was, we're</p> <p>23 going to present the data the valid data on that</p> <p>24 overriding comparison of this study, which was</p>	<p style="text-align: center;">199</p> <p>1 the nonaspirin subgroup, that there's a</p> <p>2 statistically significant result?</p> <p>3 A. So in Figure 2, No. B on the left-hand</p> <p>4 side, we are looking at patients not taking aspirin</p> <p>5 and looking at ulcer complications. And as part of</p> <p>6 the analysis plan, we were going to look at the</p> <p>7 effect of aspirin on the results of ulcer</p> <p>8 complications. And that's what this analysis shows.</p> <p>9 And in the valid data set, which is the</p> <p>10 6-month data, the number -- the incidents was lower</p> <p>11 with Celecoxib versus the NSAIDs together, and the P</p> <p>12 Value was 0.04.</p> <p>13 Q. But the article doesn't reveal that this</p> <p>14 statistically significant .04 P Value did not hold</p> <p>15 on this comparison for the entire study period?</p> <p>16 A. So once again, the objective of</p> <p>17 presenting these data was to present -- prevent --</p> <p>18 present the valid data set to physicians for</p> <p>19 physicians to understand what we saw in CLASS.</p> <p>20 That is different than presenting to the</p> <p>21 FDA. It's a whole different game. You present</p> <p>22 everything to the FDA. And in my experience, when</p> <p>23 you do a clinical trial, an animal experiment, you</p> <p>24 have to make a clinical judgment as to what you put</p>
<p style="text-align: center;">198</p> <p>1 Celebrex versus the NSAIDs. We felt that valid data</p> <p>2 was important for the medical community to see.</p> <p>3 The -- we missed on the primary endpoint.</p> <p>4 The stepdown procedure said, if you miss on the</p> <p>5 primary endpoint, the secondary -- the -- the</p> <p>6 stepdown comparisons to the individual NSAIDs, you</p> <p>7 cannot make a claim.</p> <p>8 So we were consistent with, one,</p> <p>9 following the statistical analysis plan, and the --</p> <p>10 the primary objective of presenting the data was to</p> <p>11 present the overriding comparison of Celebrex versus</p> <p>12 the NSAIDs together.</p> <p>13 Q. Can you show me where in Exhibit 3 it</p> <p>14 says that ulcer complications was the primary</p> <p>15 endpoint of CLASS?</p> <p>16 A. The phrase "primary endpoint" is not used</p> <p>17 in this manuscript.</p> <p>18 Q. My next question is, could you turn to</p> <p>19 the bottom right-hand corner of page 1251, and</p> <p>20 specifically Figure 2. And I'm looking at</p> <p>21 Figure 2B, specifically the left-hand comparison</p> <p>22 of .04.</p> <p>23 Is that computing -- communicating to the</p> <p>24 reader that with respect to complicated ulcers in</p>	<p style="text-align: center;">200</p> <p>1 in your manuscript. And what you put in is the most</p> <p>2 valid information, the most valid analysis for the</p> <p>3 medical community to get.</p> <p>4 We present the most valid analysis was</p> <p>5 the 6-month analysis, and that's what we presented.</p> <p>6 Q. But a physician wouldn't know, by just</p> <p>7 reading this article, that if you went for the</p> <p>8 entire study period on this comparison, the</p> <p>9 statistically significant finding that's reported in</p> <p>10 Figure 2B did not hold.</p> <p>11 A. What I --</p> <p>12 Q. Regardless of whether the data was valid</p> <p>13 or not --</p> <p>14 A. But I --</p> <p>15 Q. -- you wouldn't know that?</p> <p>16 A. -- think you're mischaracterizing it. I</p> <p>17 think what we don't show is that in an invalid</p> <p>18 analysis of invalid data, you get a P Value of some</p> <p>19 number.</p> <p>20 And I've never known to write a</p> <p>21 manuscript where you make a point of saying, and oh,</p> <p>22 by the way, here's an invalid data set with an</p> <p>23 invalid analysis and here's a number.</p> <p>24 Q. But the reader of this article wouldn't</p>



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<p style="text-align: center;">201</p> <p>1 know that there was additional data that was being 2 ex- -- excluded because you believed it to be 3 invalid? 4 A. I don't know what the reader of this 5 article would have known. Because at the time that 6 this was published, the -- the CLASS data had been 7 presented in multiple forms, in public. It had been 8 acknowledged that there was data beyond six months. 9 I believe analyst reports clearly acknowledged it 10 and talked about it. I believe even the Merck 11 people in a presentation in May of 2000 acknowledged 12 it. 13 So when you say what would the reader 14 know, I don't know what the reader would know. 15 Q. Can I ask you this: The invalid data, 16 the post 6-month invalid data, that was less -- even 17 though it was invalid on its face, it was less 18 favorable to Celebrex than the data presented 19 here -- 20 A. No. 21 Q. -- with respect to the nonaspirin -- 22 A. No, I disagree. 23 Q. Let me finish -- 24 A. I disagree.</p>	<p style="text-align: center;">203</p> <p>1 A. I don't recall that. 2 Q. Do you recall there were some people that 3 thought maybe there was -- physiological adaptation 4 was the reason that the 12-month data was not quite 5 as good for Celebrex as the 6-month data? 6 A. I have heard of the concept of 7 physiological adaptation. I don't recall anyone 8 internally at Searle/Pharmacia/Pfizer talking about 9 it. I do believe it may have been Dr. Goldkind 10 brought it up -- 11 Q. And Dr. -- 12 A. -- when we were at the advisory committee 13 meeting in February of 2001. 14 So long after -- so this was after the -- 15 all the data had been submitted to the FDA, multiple 16 presentations had been -- had been made to the 17 public acknowledging there was data beyond six 18 months. The manuscript had been published. We're 19 now into February 2001. That's where I believed 20 I -- I heard it. 21 Q. And is it correct that Dr. Goldkind was 22 one of the FDA reviewers for the advisory committee 23 on -- on this data? 24 A. As I recall, he gave a presentation.</p>
<p style="text-align: center;">202</p> <p>1 Q. -- complete the question, sir -- 2 A. Okay. 3 Q. -- just so you're answering, you know, 4 the right question. 5 With respect to this comparison in 6 Figure 2B on the left-hand side, reporting a P Value 7 of .04 for the nonaspirin subgroup on the 8 complicated ulcer comparison, with respect to this 9 data, the invalid post 6-month data, the data for 10 the entire study is less favorable to Celebrex than 11 what's reported here; is that correct, sir? 12 MR. HOFF: Objection to form. 13 BY THE WITNESS: 14 A. Once you are beyond six months into an 15 invalid data set, to even say something looks worse 16 or better than something else is nonsensical because 17 you're looking at virtually nothing. It doesn't 18 mean anything. 19 BY MR. SAHAM: 20 Q. There are individuals at Pfizer that were 21 not persuaded by the informative censoring bias 22 explanation as to why the 12-month data was less 23 favorable than the 6-month data; is that correct, 24 sir?</p>	<p style="text-align: center;">204</p> <p>1 Whether he was officially considered the reviewer, I 2 don't know, but he gave the present- -- a 3 presentation. 4 Q. And -- and a statistical reviewer by the 5 name of Dr. Lu also gave a presentation? 6 A. That -- 7 Q. Hong Lu? 8 A. That sounds familiar. 9 Q. And they both rejected the bias argument 10 in -- in -- in favor of -- strike that. 11 And they both rejected the use of the 12 6-month data in the informative censoring analysis 13 for the purposes of communicating the data to the 14 FDA? 15 A. I don't recall exactly what they said. 16 Q. Do you recall ultimately that the FDA 17 rejected the use of the 6-month data with respect to 18 the SNDA? 19 A. Rejected the 6-month data? They did not 20 reject the 6-month data. 21 Q. They required that the full entire study 22 data be reported at the advisory committee as part 23 of the SNDA to change the label of Celebrex; is that 24 right?</p>



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<p style="text-align: center;">205</p> <p>1 A. They didn't require anything for our 2 presentation at the advisory committee in 3 February of 2001. 4 Q. They expressed that you should present 5 the entire data, not just the 6-month data; is that 6 correct, sir? 7 A. We had a premeeting discussion with them. 8 They were now familiar with all the data, as were 9 we. We all realized it was a complicated data set 10 with a complicated study that no one ever had 11 conducted before. And we discussed, how do we best 12 present the data so that the audience could fully 13 understand the results of the trial, our logic, 14 the -- and the process we went through for 15 identifying the valid data set. 16 Their suggestion was, start big and then 17 hone in on the 6-month data, as opposed to, start 18 just with the 6-month data and then talk about the 19 12-month data. 20 So really, there was no difference 21 between what they thought and what we thought. It 22 was just the sequence was up for discussion, and it 23 was a consensus, not a mandate, not a 24 recommendation. By consensus, we, with the FDA,</p>	<p style="text-align: center;">207</p> <p>1 correct? 2 A. That's not how I read this. 3 Q. So you're -- 4 A. I read -- 5 Q. -- saying the main outcome measure here 6 is -- 7 A. Could I finish? 8 MR. HOFF: Wait a second. 9 BY THE WITNESS: 10 A. Could I finish? 11 MR. HOFF: Let him finish -- 12 BY THE WITNESS: 13 A. Could I finish -- 14 MR. HOFF: -- finish his answer. 15 BY THE WITNESS: 16 A. -- my comment? 17 What I read here is the -- 18 MR. SAHAM: Move to strike as nonresponsive. 19 MR. HOFF: He didn't finish his answer. 20 MR. SAHAM: And he's not answering my question, 21 John. 22 MR. HOFF: You're not letting him. You're -- 23 you keep interrupting him. 24 MR. SAHAM: Because my question is very</p>
<p style="text-align: center;">206</p> <p>1 said, yeah, that makes sense. We'll start this way 2 to present it so the people can understand the 3 study, all the data and our process for identifying 4 the valid data set. 5 Q. Now, looking at Exhibit 3, the main 6 outcome measure on the first page, which is, I 7 think, the main outcome measure, the combined 8 endpoint of complicated ulcers and symptomatic 9 ulcers together; is that correct? 10 A. I'm sorry, could you repeat your 11 question? 12 Q. I'm just looking at the main outcome 13 measure in the -- I guess you call it the abstract 14 in the front of the article. The main outcome 15 measure, it says, "Incidence of prospectively 16 defined symptomatic upper GI ulcers and ulcer 17 complications (bleeding, perforation, and 18 obstruction) and other adverse effects during the 19 6-month treatment period." 20 Do you see that? 21 A. I do see that. 22 Q. And that's not the primary outcome of the 23 CLASS trial, that's the combined endpoint of 24 complicated ulcers and symptomatic ulcers; is that</p>	<p style="text-align: center;">208</p> <p>1 straightforward, and he's going -- 2 MR. HOFF: No, you said, doesn't it say this, 3 and he says, that's not how I read it. And he's 4 going to tell what he -- how he reads it. So you're 5 getting an answer to this question. 6 MR. SAHAM: I'll withdraw the question. See if 7 we can get a -- come to some consensus on what I'm 8 asking. 9 BY MR. SAHAM: 10 Q. Is it your testimony, sir, that the main 11 outcome measure listed here in Exhibit 3 is the same 12 as the primary outcome measure of the CLASS study or 13 the coprimary endpoints in the CLASS study? 14 A. As I read this in this manuscript, it 15 says, Incidents of prospectively defined ulcer 16 complications. 17 That is in here, which is consistent with 18 what was identified as the primary endpoint of the 19 protocol. 20 Q. Wasn't the primary -- but -- but this 21 also includes symptomatic GI ulcers, which are a 22 less severe ulcer than a complicated ulcer; isn't 23 that correct? This is a combined endpoint of those 24 two endpoints?</p>



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<p style="text-align: center;">209</p> <p>1 A. As I was --</p> <p>2 MR. WEISS: Objection --</p> <p>3 MR. HOFF: Objection to form.</p> <p>4 BY THE WITNESS:</p> <p>5 A. As I was trying to relate to you earlier,</p> <p>6 as I read this sentence, I don't read this as</p> <p>7 prospectively the combined endpoint. I read it as</p> <p>8 prospectively defined symptomatic GI ulcers</p> <p>9 separate, and ulcer complications separate. And</p> <p>10 then in the statistical methods, it says, we put</p> <p>11 those together as a combined endpoint.</p> <p>12 That's how I read this.</p> <p>13 BY MR. SAHAM:</p> <p>14 Q. But that -- this doesn't -- at least this</p> <p>15 main outcome measure here and -- and/or the whole</p> <p>16 article, this doesn't reveal that the primary</p> <p>17 outcome measure of the CLASS study per the protocol</p> <p>18 is complicated ulcers by themselves?</p> <p>19 A. The pri- -- it does not use that</p> <p>20 terminology.</p> <p>21 Q. Okay. And -- and do you recall that JAMA</p> <p>22 required or had a protocol checklist that required</p> <p>23 if the main outcome measure was something different</p> <p>24 than the primary objective of a -- a trial, that it</p>	<p style="text-align: center;">211</p> <p>1 BY MR. SAHAM:</p> <p>2 Q. And I ask you if you recognize these</p> <p>3 article -- or these letters?</p> <p>4 The question is, do you recognize these</p> <p>5 letters?</p> <p>6 A. No, I do not.</p> <p>7 Q. Do you recall writing letters to -- or</p> <p>8 drafting letters to an editor at U.S. News &amp; World</p> <p>9 Report or a Michael Wolfe?</p> <p>10 A. No, I do not.</p> <p>11 Q. And in this letter, which does bear your</p> <p>12 signa- -- signatory, although it's not signed, it</p> <p>13 says it's from you -- it says -- in the first letter</p> <p>14 on the first page, it says, "All interactions</p> <p>15 between CLASS study authors and the editors of JAMA</p> <p>16 concerning this submission were conducted strictly</p> <p>17 according to standard JAMA protocols."</p> <p>18 Do you believe that's an accurate</p> <p>19 statement?</p> <p>20 A. Where exactly are you reading at?</p> <p>21 Q. The -- it's the first sentence of the</p> <p>22 first paragraph -- or I'm sorry, it's not the</p> <p>23 first -- it's the third -- first sentence of the</p> <p>24 third paragraph. Do you see, "I would like to set</p>
<p style="text-align: center;">210</p> <p>1 needed to be disclosed in the article?</p> <p>2 A. I -- I'm not familiar with a checklist</p> <p>3 from JAMA about that type of thing.</p> <p>4 Q. I want to show you what I'm marking as</p> <p>5 Plaintiffs' Exhibit 258.</p> <p>6 (WHEREUPON, a certain document was</p> <p>7 marked Plaintiffs' Deposition</p> <p>8 Exhibit No. 258, for identification,</p> <p>9 as of 12/10/2010.)</p> <p>10 BY MR. SAHAM:</p> <p>11 Q. Could you please take a look at</p> <p>12 Plaintiffs' Exhibit 258.</p> <p>13 MR. SAHAM: Oh, I gave you two. Sorry, John.</p> <p>14 Can you send one back?</p> <p>15 Thank you.</p> <p>16 Exhibit 258 is -- appears to be a</p> <p>17 conglomerate of two letters. The first letter is</p> <p>18 dated September 18, 2001, and it's -- it's not</p> <p>19 signed, but it's from Steven Geis to Stacey Schultz,</p> <p>20 senior editor U.S. News &amp; World Report.</p> <p>21 And then the second two pages of the</p> <p>22 exhibit, last three Bates numbers 037 to 038, is a</p> <p>23 letter from yourself to M. Michael Wolfe dated</p> <p>24 August 17th, 2001.</p>	<p style="text-align: center;">212</p> <p>1 the record straight"?</p> <p>2 And then you say, "All interactions</p> <p>3 between CLASS study authors and the editors of JAMA</p> <p>4 concerning this submission were conducted strictly</p> <p>5 according to standard JAMA protocols"?</p> <p>6 A. I'm really sorry, I can't find the</p> <p>7 sentence. I'm in paragraph -- the paragraph begins</p> <p>8 with what? Oh, I see it. There. There. That's --</p> <p>9 Q. You got it?</p> <p>10 A. Oh, I see it.</p> <p>11 Q. And I'm asking you if you believe that to</p> <p>12 be an accurate statement?</p> <p>13 A. So let me clarify something. I -- I</p> <p>14 have -- don't believe I've ever seen this before.</p> <p>15 Although somebody typed my name at the bottom, I</p> <p>16 won't acknowledge this came from me. Okay.</p> <p>17 Having said that, you're asking me, do I</p> <p>18 believe that the interactions were conducted</p> <p>19 according to standard JAMA protocols? Yes, I do</p> <p>20 believe that --</p> <p>21 Q. Okay. And turn- --</p> <p>22 A. -- to be the case.</p> <p>23 Q. -- turning to the second page, the letter</p> <p>24 that seems to be -- at least has a signature line</p>



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<p>213</p> <p>1 for you where you didn't sign, but there is a</p> <p>2 signature block for G. Steven Geis, Ph.D., M.D.,</p> <p>3 Group Vice President, Clinical Research.</p> <p>4 In the third paragraph there, it says,</p> <p>5 "The interaction with the editors of JAMA concerning</p> <p>6 this submission follow standard JAMA process?"</p> <p>7 Do you see that?</p> <p>8 A. I do.</p> <p>9 Q. Do you believe that to be an accurate</p> <p>10 statement?</p> <p>11 A. So in this letter that I don't -- haven't</p> <p>12 written or I don't believe I wrote, I don't recall</p> <p>13 having seen this and didn't sign, that sentence, I</p> <p>14 believe, is true.</p> <p>15 Q. Okay. Now, I would like to show you what</p> <p>16 I'm marking as Plaintiffs' Exhibit 259.</p> <p>17 (WHEREUPON, a certain document was</p> <p>18 marked Plaintiffs' Deposition</p> <p>19 Exhibit No. 259, for identification,</p> <p>20 as of 12/10/2010.)</p> <p>21 MR. SAHAM: Could you please take a look at</p> <p>22 Plaintiffs' Exhibit 259, which for the record, bears</p> <p>23 Bates numbers DEFS 01714080 through 249. And it's</p> <p>24 entitled JAMA Author Instructions, updated</p>	<p>215</p> <p>1 these first ten pages that you, I believe,</p> <p>2 accurately pointed out, say 1 of 10.</p> <p>3 Do you recognize these?</p> <p>4 A. Okay. So do I recognize pages 1</p> <p>5 through 10? No, I do not.</p> <p>6 Q. Okay. Now, looking at the next two pages</p> <p>7 after that, the 1 of 2, so you're looking at</p> <p>8 Bates number 090 through 091.</p> <p>9 Do you recognize those?</p> <p>10 A. I don't.</p> <p>11 Q. Okay. And those are labeled Checklist</p> <p>12 for Authors Submitting Reports of --</p> <p>13 A. Uh-huh.</p> <p>14 Q. -- Randomized Controlled Trials to JAMA?</p> <p>15 A. Yes.</p> <p>16 Q. You were an author who submitted such an</p> <p>17 article, correct, or report?</p> <p>18 A. I was one of the authors that</p> <p>19 participated in this submission, yes.</p> <p>20 Q. Okay. And then continuing on,</p> <p>21 specifically the Bates numbers I want to refer you</p> <p>22 to, if you -- if you start at Bates number 095,</p> <p>23 which is entitled JAMA Author Instructions,</p> <p>24 Preparing Reports of Randomized Controlled Trials --</p>
<p>214</p> <p>1 January 5, 2000.</p> <p>2 BY MR. SAHAM:</p> <p>3 Q. And I'd specifically -- I realize it's a</p> <p>4 lengthy document. I'd ask you just generally, do</p> <p>5 you recognize it as a -- as a document you've seen</p> <p>6 before?</p> <p>7 A. I'm a little confused because the</p> <p>8 first -- this -- you handed me this stack of paper.</p> <p>9 And the first thing says what you'd described as</p> <p>10 JAMA Author Instructions, updated January 5, 2000.</p> <p>11 And it says pages 1 of 10. So, yes, there are ten</p> <p>12 pages here.</p> <p>13 But then behind it, it appears to be a</p> <p>14 second document saying JAMA checklist, 1999,</p> <p>15 pages -- page 1 of 2. So the first says 2000. The</p> <p>16 second says 1999. So I don't know if they're the --</p> <p>17 together.</p> <p>18 Q. Well, I'll represent to you that the</p> <p>19 Bates numbers in the bottom right-hand corner are</p> <p>20 all consecutive.</p> <p>21 A. Yes.</p> <p>22 Q. Whether they're different documents or</p> <p>23 not, the Bates numbers all run consecutively and we</p> <p>24 can break down the document, you know, starting with</p>	<p>216</p> <p>1 do you see that?</p> <p>2 A. So we're skipping 092 through 094?</p> <p>3 Q. Correct. For now, anyway.</p> <p>4 A. Okay.</p> <p>5 Q. So I'm looking at 095 --</p> <p>6 A. Yes.</p> <p>7 Q. -- the next five pages that run</p> <p>8 through 100, these JAMA Author Instructions.</p> <p>9 Do you see that?</p> <p>10 A. Uh-huh, I do see that.</p> <p>11 Q. And specifically, if you turn to the</p> <p>12 third page of that part of the document,</p> <p>13 Bates number 097, or page 2 of 5 of the</p> <p>14 instructions -- do you see that?</p> <p>15 A. I do.</p> <p>16 Q. And down at the bottom, there's a</p> <p>17 number 7, Main Outcome Measure(s); is that correct?</p> <p>18 A. Yes.</p> <p>19 Q. And it says, quote, The primary study</p> <p>20 outcome measurement(s) should be indicated as</p> <p>21 planned before data collection began. If the</p> <p>22 manuscript does not report the main plan collection</p> <p>23 of a study, this fact should be stated and the</p> <p>24 reason indicated.</p>



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<p style="text-align: center;">217</p> <p>1 And my question to you, in Wolfe</p> <p>2 Exhibit 3, the JAMA article, is there an</p> <p>3 explanation, as described here in No. 7, that</p> <p>4 comports with this JAMA author instruction?</p> <p>5 A. The first sentence says, "The primary</p> <p>6 study outcome measurement(s) should be indicated as</p> <p>7 planned before data collection began."</p> <p>8 That is what we did in the protocol on</p> <p>9 the statistical analysis plan. We stated what the</p> <p>10 primary outcome was, and it -- it was indicated as</p> <p>11 planned before the data collection began. So we did</p> <p>12 do that.</p> <p>13 If the manuscript does not report the</p> <p>14 main planned outcomes, this fact should be stated.</p> <p>15 We do report the main planned outcomes in JAMA</p> <p>16 because we do report the incidents of ulcer</p> <p>17 complications. So we did comply with it.</p> <p>18 Q. But you didn't describe those complicated</p> <p>19 ulcers as the primary endpoint in the JAMA article,</p> <p>20 correct?</p> <p>21 A. It doesn't say that. It doesn't say that</p> <p>22 that's what -- a must. They just say, did you</p> <p>23 identify it before you collected the data, which we</p> <p>24 did, and if we're not going to include that in the</p>	<p style="text-align: center;">219</p> <p>1 Q. And this is the document you pointed out,</p> <p>2 being the second part of this that has one of two,</p> <p>3 and it's labeled Checklist for Authors Submitting</p> <p>4 Reports of Randomized Controlled Trials to JAMA.</p> <p>5 Do you see that?</p> <p>6 A. I do.</p> <p>7 Q. And if you turn to the second page,</p> <p>8 specifically No. 20, in the checklist, it says,</p> <p>9 "State specific interpretation of study findings,</p> <p>10 including sources of bias and imprecision (internal</p> <p>11 validity) and discussion of external validity,</p> <p>12 including appropriate quantitative measures when</p> <p>13 possible."</p> <p>14 Now, you didn't comply with this</p> <p>15 requirement because you didn't describe in the JAMA</p> <p>16 article, Exhibit 3, that the bias was the reason for</p> <p>17 excluding the second six months of data; is that</p> <p>18 correct, sir?</p> <p>19 MR. HOFF: Objection to form.</p> <p>20 BY THE WITNESS:</p> <p>21 A. I need to read this to make sure I</p> <p>22 understand fully what this means.</p> <p>23 I think we were in compliance with this.</p> <p>24</p>
<p style="text-align: center;">218</p> <p>1 manuscript, we must tell them why. But we did</p> <p>2 include it in the manuscript.</p> <p>3 Q. You just didn't identify it as the</p> <p>4 primary endpoint?</p> <p>5 A. It's not identified as the primary</p> <p>6 endpoint in the manuscript, but we are consistent</p> <p>7 with this page that appears to be guidelines of --</p> <p>8 of what you're supposed to do, preparing a report of</p> <p>9 a randomized control trial.</p> <p>10 Q. Turn- -</p> <p>11 A. Yes, I think we were consistent with what</p> <p>12 they requested.</p> <p>13 Q. Turning back to Bates number 090 through</p> <p>14 091, the second part of the document, the JAMA 1999,</p> <p>15 page 1 of 2, Checklist for Authors Submitting</p> <p>16 Reports of Randomized Controlled Trials to JAMA.</p> <p>17 Are you with me?</p> <p>18 A. No, I'm not.</p> <p>19 Q. Tell me when you're with me.</p> <p>20 A. So is the bottom right-hand corner the</p> <p>21 Bates number?</p> <p>22 Q. Yeah. 090, the last three.</p> <p>23 Are you with me?</p> <p>24 A. Yes.</p>	<p style="text-align: center;">220</p> <p>1 BY MR. SAHAM:</p> <p>2 Q. How did you describe the bias that you've</p> <p>3 testified about earlier in Exhibit 3?</p> <p>4 A. There are biases in data sets. Even in</p> <p>5 what we would consider valid data sets, there were</p> <p>6 biases. So, for example, we think that the -- the</p> <p>7 high level of aspirin use in the -- in the study was</p> <p>8 a bias against Celebrex, even in the valid data set.</p> <p>9 So we did describe a bias for what we</p> <p>10 believed was the valid data set, which is what they</p> <p>11 asked for.</p> <p>12 We talked about potential biases when we</p> <p>13 looked at the baseline demographics comparing the</p> <p>14 two treatment groups. So we did talk about biases</p> <p>15 with respect to what we believed was the valid data</p> <p>16 set. So we were in compliance with this.</p> <p>17 Q. But the bias you talked about earlier</p> <p>18 that you believe rendered the second six months of</p> <p>19 data invalid, that bias is not discussed in Wolfe</p> <p>20 Exhibit 3, correct?</p> <p>21 A. We do not present the data beyond six</p> <p>22 months because we believe it is invalid.</p> <p>23 Q. And you don't explain how the bias led to</p> <p>24 invalid data that you have described earlier; is</p>



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<p>221</p> <p>1 that correct, sir?</p> <p>2 A. I think it is very common to -- to not</p> <p>3 present all data from a trial in a publication. And</p> <p>4 you don't have to go through a laundry list as to</p> <p>5 why you aren't presenting the data that you don't</p> <p>6 think is valid.</p> <p>7 So we are consistent with precedent. We</p> <p>8 are consistent with practice. And I believe we are</p> <p>9 consistent with this.</p> <p>10 Q. But the reason you didn't present that</p> <p>11 additional six months of data was because you</p> <p>12 believed it to be bias, correct, sir?</p> <p>13 A. We believe -- we believe that the data</p> <p>14 beyond six months was bias, yes.</p> <p>15 Q. And you --</p> <p>16 A. That's why we didn't present it.</p> <p>17 Q. And you didn't describe that bias, the</p> <p>18 bias that caused, in your opinion, the six -- second</p> <p>19 6-month data to be invalid? You did not describe</p> <p>20 that bias in the JAMA article, Wolfe Exhibit 3,</p> <p>21 correct, sir?</p> <p>22 A. We didn't describe that bias, but we did</p> <p>23 describe biases with respect to the valid data set</p> <p>24 in compliance with this No. 20.</p>	<p>223</p> <p>1 BY MR. SAHAM:</p> <p>2 Q. Could you please take a look at</p> <p>3 Plaintiffs' Exhibit 260.</p> <p>4 MR. SAHAM: And for the record, Plaintiffs'</p> <p>5 Exhibit 260 is a two-page e-mail chain bearing</p> <p>6 Bates numbers DEFS 00169725 through 726. And the</p> <p>7 top e-mail in the chain is authored by George S.</p> <p>8 Geis. And it's dated June 21st, 2002. It's to</p> <p>9 Felix Arellano, Goran Ando and others.</p> <p>10 BY MR. SAHAM:</p> <p>11 Q. And specifically, I'd ask you if you</p> <p>12 recognize Exhibit 260?</p> <p>13 A. I don't remember this e-mail and the</p> <p>14 preceding e-mails.</p> <p>15 Q. But this is an e-mail that you would have</p> <p>16 sent on June 21st, 2002?</p> <p>17 A. Well, it is an e-mail that looks like it</p> <p>18 came from me on 2000 -- June 21st, 2002.</p> <p>19 Q. And you would have sent this in the</p> <p>20 capacity of your employment at Pharmacia?</p> <p>21 A. I don't recall either way because I don't</p> <p>22 remember this.</p> <p>23 Q. Okay. And you write to Felix Arellano</p> <p>24 and the others listed, But the point I'm trying to</p>
<p>222</p> <p>1 Q. But the bias that you testified about</p> <p>2 earlier is not described in Exhibit 3?</p> <p>3 MR. HOFF: Objection to form.</p> <p>4 BY THE WITNESS:</p> <p>5 A. So you -- you'll have to remind me the</p> <p>6 bias I testified earlier to.</p> <p>7 BY MR. SAHAM:</p> <p>8 Q. I'm just talking about -- we've talked</p> <p>9 for a long time now about how you believed that the</p> <p>10 bias after six months rendered that data invalid.</p> <p>11 Am I correctly summarizing your</p> <p>12 testimony?</p> <p>13 A. Yes, that's correct.</p> <p>14 Q. And that bias that rendered the second</p> <p>15 6-month data invalid is not referenced in Wolfe</p> <p>16 Exhibit 3, the JAMA article which you coauthored?</p> <p>17 A. That's correct. But I will also say we</p> <p>18 were in compliance with No. 20 on page 2.</p> <p>19 Q. I want to show you what I'm marking as</p> <p>20 Plaintiffs' Exhibit 260.</p> <p>21 (WHEREUPON, a certain document was</p> <p>22 marked Plaintiffs' Deposition</p> <p>23 Exhibit No. 260, for identification,</p> <p>24 as of 12/10/2010.)</p>	<p>224</p> <p>1 make in the figure is that the NSAID rate decreased</p> <p>2 with time - which was unexpected. This, in turn,</p> <p>3 put in question the validity of the analyses of the</p> <p>4 longer term data. The reader needs to understand</p> <p>5 this point to understand why the CLASS authors</p> <p>6 published the 6-month analyses as the initial</p> <p>7 manuscript.</p> <p>8 Do you believe that that's an accurate</p> <p>9 statement?</p> <p>10 A. So I believe that you read this</p> <p>11 correctly, but we need to talk about -- I need to</p> <p>12 answer this in light of when this was written and</p> <p>13 what it's referred to.</p> <p>14 So assuming that this is all correct and</p> <p>15 I wrote this, we are now in June 21st, 2002. The</p> <p>16 CLASS manuscript has been published. It is in</p> <p>17 around -- and all the data has been submitted to the</p> <p>18 FDA. The data has been vetted in public at the</p> <p>19 advisory committee meeting in February of 2001. And</p> <p>20 then in August of 2001, the issue begins to arise in</p> <p>21 the -- in the lay press about data beyond six</p> <p>22 months.</p> <p>23 So now, at this time, the question is</p> <p>24 being asked, why did you -- specifically, why didn't</p>





<p>225</p> <p>1 you include -- why did you believe the 6-month data</p> <p>2 was the most valid?</p> <p>3 Fast forward now to 2002. A -- letters</p> <p>4 are written to the editor at BMJ asking, in part,</p> <p>5 that question. So now you have a specific question</p> <p>6 on the table: Why did you believe the 6-month data</p> <p>7 was the most valid data?</p> <p>8 I was going to write the response to that</p> <p>9 question. And specifically, in response to that</p> <p>10 question, I was putting together my response, people</p> <p>11 were reviewing it.</p> <p>12 So in the sense that the question was</p> <p>13 asked, this -- I'm saying, in order for them to</p> <p>14 understand what I'm saying in my response to the</p> <p>15 letter, the reader needs to understand X, Y and Z.</p> <p>16 So this is completely two years after the</p> <p>17 JAMA manuscript has been published. But</p> <p>18 specifically the question has been asked, why do you</p> <p>19 think the 6-month data is more valid?</p> <p>20 Q. And that question is not answered by</p> <p>21 Wolfe Exhibit 3; is that correct, sir, the JAMA</p> <p>22 article from September of 2000?</p> <p>23 A. We did not put the explanation of why the</p> <p>24 6-month data was the most valid data in the</p>	<p>227</p> <p>1 only used six months of, you know -- or not six</p> <p>2 months, but half of -- approximately half of a data</p> <p>3 set chronologically?</p> <p>4 MR. HOFF: Objection to form.</p> <p>5 BY THE WITNESS:</p> <p>6 A. Could you repeat the question?</p> <p>7 BY MR. SAHAM:</p> <p>8 Q. I'll -- I'll ask a better question.</p> <p>9 Other than CLASS, do you recall any other</p> <p>10 clinical trials you did where you, you know, just</p> <p>11 took, you know, a portion of the entire study period</p> <p>12 and reported it in a -- an academic journal without</p> <p>13 saying that's what you were doing?</p> <p>14 A. We -- in my experience, as I remember --</p> <p>15 and I'd have to go through all my manuscripts that</p> <p>16 I've ever written -- I published and --</p> <p>17 participating and published what we believed was the</p> <p>18 most valid data. And I don't remember ever feeling</p> <p>19 that what we were doing with CLASS was anywhere</p> <p>20 different from that.</p> <p>21 Q. I'm going to show you what I'm marking as</p> <p>22 Plaintiffs' Exhibit 261.</p> <p>23</p> <p>24</p>
<p>226</p> <p>1 manuscript in the summer of 2000.</p> <p>2 Q. And you wrote, in the summer of 2002,</p> <p>3 that the reader needs to understand this point to</p> <p>4 understand why the CLASS authors, being yourself,</p> <p>5 published the 6-month analyses in Exhibit 3; is that</p> <p>6 correct?</p> <p>7 A. So the --</p> <p>8 MR. HOFF: Objection to form.</p> <p>9 Go ahead.</p> <p>10 BY THE WITNESS:</p> <p>11 A. So the -- the 2002 is a completely</p> <p>12 different audience and completely different setting.</p> <p>13 When writing the CLASS manuscript, we did what we</p> <p>14 always do, publish what we believe is the most valid</p> <p>15 data, which we did.</p> <p>16 Two years later, someone asked the</p> <p>17 question: Why did you consider that the most valid</p> <p>18 data? We were writing to answer that question. And</p> <p>19 we were saying, how do we effectively communicate</p> <p>20 that for the reader?</p> <p>21 That's all this was.</p> <p>22 BY MR. SAHAM:</p> <p>23 Q. Did you ever do a clinical trial, any</p> <p>24 other clinical trial other than CLASS, where you</p>	<p>228</p> <p>1 (WHEREUPON, a certain document was</p> <p>2 marked Plaintiffs' Deposition</p> <p>3 Exhibit No. 261, for identification,</p> <p>4 as of 12/10/2010.)</p> <p>5 BY MR. SAHAM:</p> <p>6 Q. Could you please take a look at</p> <p>7 Plaintiffs' Exhibit 261.</p> <p>8 MR. SAHAM: And for the record, Plaintiffs'</p> <p>9 Exhibit 261 is a three-page e-mail chain bearing</p> <p>10 Bates numbers DEFS 01868956 through 58.</p> <p>11 And the e-mail on the first page, not the</p> <p>12 top one from Lefkowitz that says, "Understood, JL,"</p> <p>13 but the e-mail below that appears to be from George</p> <p>14 S. Geis, dated Sunday, April 22, 2001, to James</p> <p>15 Lefkowitz, Kenneth Verburg and also to George S.</p> <p>16 Geis. And there's additional e-mails in the chain</p> <p>17 from Goran Ando and others.</p> <p>18 BY MR. SAHAM:</p> <p>19 Q. I'd ask you -- my first question is, do</p> <p>20 you recognize this e-mail?</p> <p>21 I asked you if you recognize this e-mail</p> <p>22 chain?</p> <p>23 A. I do not.</p> <p>24 Q. Okay. And do you believe -- or strike</p>



<p>229</p> <p>1 that question.</p> <p>2 Is this an e-mail that you -- or an</p> <p>3 e-mail chain that you received and wrote at</p> <p>4 Pharmacia on or about April 21st and 22nd, 2001?</p> <p>5 A. I don't recall it, but it appears to be.</p> <p>6 Q. Okay. And you have no reason to dispute</p> <p>7 that this is what -- it is what it appears to be?</p> <p>8 A. Either way, I don't remember.</p> <p>9 Q. And you wrote -- at least according to</p> <p>10 the e-mail that has your name on it as an author,</p> <p>11 you wrote on April 22nd, But a word of caution --</p> <p>12 we, as clinical, can't get caught in the trap of</p> <p>13 implying to our folks or to others that the non-ASA</p> <p>14 analysis was a predefined as a primary analysis. In</p> <p>15 fact, I don't think it was defined as secondary. If</p> <p>16 we make the implication and are called on it - we</p> <p>17 will lose a lot of credibility.</p> <p>18 Do you believe that to be an accurate</p> <p>19 statement?</p> <p>20 A. So I believe you read this correctly.</p> <p>21 And so the question is, do I believe what was</p> <p>22 written here is accurate?</p> <p>23 So let me tell you what I believe was</p> <p>24 going on at this time in terms -- this appears to be</p>	<p>231</p> <p>1 Q. So you believe this is an accurate</p> <p>2 statement; is that correct, sir?</p> <p>3 A. Well, it's an accurate statement in terms</p> <p>4 of where I believe my -- my mind was at at this</p> <p>5 time. We are now in -- in discussions with FDA</p> <p>6 about the label, and we want to make sure there is</p> <p>7 precision in understanding the analyses of the</p> <p>8 study.</p> <p>9 Q. So although you don't remember writing</p> <p>10 this, it's something that you believe to be true?</p> <p>11 A. Yes.</p> <p>12 Q. And it's certainly under your -- you're</p> <p>13 attributed to be the author as having sent this</p> <p>14 e-mail, correct?</p> <p>15 A. That's what it appears to be.</p> <p>16 Q. Okay. And the people you sent it to are</p> <p>17 people who were on your team; is that correct --</p> <p>18 Dr. Lefkowitz and Dr. Verbarg?</p> <p>19 A. Yes, that's correct.</p> <p>20 Q. So you don't have any reason to believe</p> <p>21 you didn't receive and send this e-mail -- received</p> <p>22 the prior e-mail and forwarded it on in the ordinary</p> <p>23 scope of your employment at Pharmacia?</p> <p>24 A. Well, I don't remember it either way.</p>
<p>230</p> <p>1 in reference to a proposed label change to Celebrex</p> <p>2 after having made the submission of all the data,</p> <p>3 after having presented all the data at the</p> <p>4 February advisory committee meeting in 2001. And</p> <p>5 now we were talking about proposed wording -- a</p> <p>6 proposed label change that we made to the FDA.</p> <p>7 In those discussions, there was questions</p> <p>8 of clarity, of -- of precision as to what the</p> <p>9 analysis plan was and what were the primary</p> <p>10 endpoints, what was the primary analysis.</p> <p>11 And so there was a process where we were</p> <p>12 going through to be as accurate as possible and</p> <p>13 consistent with the protocol as possible so we</p> <p>14 did not -- so someone did not get the wrong</p> <p>15 impression.</p> <p>16 And this was, as part of that, just</p> <p>17 saying a word of caution. We want to make sure that</p> <p>18 what we state is consistent with what we did in the</p> <p>19 protocol and the statistical analysis plan.</p> <p>20 So in that context, yes, this was</p> <p>21 correct.</p> <p>22 Q. And you believed --</p> <p>23 A. We wanted to make sure we were consistent</p> <p>24 with what we said we were going to do.</p>	<p>232</p> <p>1 Q. But given that it -- it -- it -- it</p> <p>2 appears to be an e-mail that you received and</p> <p>3 sent -- I mean, do you have any reason to dispute</p> <p>4 that?</p> <p>5 A. It appears to be -- I don't remember it</p> <p>6 either way. It just appears to be a -- a series of</p> <p>7 e-mails that -- that I was copied on, and I wrote</p> <p>8 the one at the top. That's what it appears to me.</p> <p>9 But I don't remember it.</p> <p>10 Q. And it seems to indicate that the non-ASA</p> <p>11 analysis was not predefined in the protocol as</p> <p>12 either a primary or a sec- --</p> <p>13 A. No, that's not --</p> <p>14 Q. -- secondary analysis?</p> <p>15 A. -- that's not what this says. So let's</p> <p>16 get back to clarity and intent of what these words</p> <p>17 are.</p> <p>18 What I was saying was predefined as a</p> <p>19 primary, not predefined. It was clearly, as I</p> <p>20 remembered it, predefined that we were going to do</p> <p>21 an effective aspirin on the analysis of ulcer</p> <p>22 complications. That clearly was predefined.</p> <p>23 But what I was cautioning is to say, it</p> <p>24 was not -- as I remembered, it was not predefined as</p>



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<p>233</p> <p>1 a primary analysis. And I was basically saying, go 2 back and make sure my mind is correct on this, 3 because we don't want people to think that we were 4 being inconsistent with the protocol. 5 Q. Right. Let -- 6 A. Let me be clear. Aspirin was -- the 7 effect of aspirin was predefined. And I was saying, 8 make sure people understand it was not predefined as 9 a primary analysis. 10 Q. And I -- I think you may have misheard my 11 question, so I'm going to have the court -- 12 A. Okay. 13 Q. -- reporter read it back to you and see 14 if you -- 15 A. Please. 16 Q. -- can answer it in a yes or no fashion. 17 MR. SAHAM: Would you mind reading back the 18 question. 19 (WHEREUPON, the record was read by 20 the reporter.) 21 BY THE WITNESS: 22 A. And so my answer is, you're incorrect. 23 BY MR. SAHAM: 24 Q. It was the primary --</p>	<p>235</p> <p>1 in the CLASS protocol and statistical analysis plan. 2 So I was just saying, there's so much 3 going on. We're now a year and a half out. I don't 4 want to depend on my memory in terms of this word. 5 You need to check it. 6 Q. Would you please turn back to Wolfe 7 Exhibit 3, the JAMA article. And specifically, we 8 were looking at Figure 2, Section B on the left-hand 9 side about the nonaspirin subgroup. 10 There's no indication in Wolfe Exhibit 3 11 that this nonaspirin analysis was not predefined as 12 a primary endpoint in the CLASS protocol; is that 13 correct, sir? 14 A. Could you repeat the question? I'm 15 sorry. 16 MR. SAHAM: Could -- could you read it back, 17 ma'am. 18 (WHEREUPON, the record was read by 19 the reporter.) 20 BY THE WITNESS: 21 A. That is correct. But I would also point 22 out that in the JAMA manuscript under Main Outcome 23 Measures, we don't talk about aspirin, either. 24 MR. SAHAM: Okay. And I would move to strike</p>
<p>234</p> <p>1 A. It -- 2 Q. -- or secondary e-mail? 3 A. It was predefined as an analysis. In the 4 protocol, we don't specifically use the word 5 secondary. 6 Q. But it wasn't -- the non-ASA analysis was 7 not predefined as a primary analysis; is that 8 correct, sir? 9 A. That is correct. 10 Q. Okay. And, in fact, you wrote here, in 11 fact, I don't think it was defined as a secondary? 12 A. So we are talking about a year after -- 13 how many years after the protocol and the stats plan 14 was written? So -- so let me -- let me give you 15 some context. 16 In the year 2000, I was responsible for 17 two full NDAs and two SNDAs, so I had teams working 18 on results of multiple protocols, multiple results 19 and multiple submissions. 20 I could not remember precisely the 21 wording in any one of those protocols because there 22 were so many. And I had staff working on it. I was 23 saying, go back and check this. I don't remember 24 what wording we used in terms of primary, secondary,</p>	<p>236</p> <p>1 the second part of the answer as nonresponsive. 2 I want to show you what I'm marking as 3 Plaintiffs' Exhibit 262. 4 (WHEREUPON, a certain document was 5 marked Plaintiffs' Deposition 6 Exhibit No. 262, for identification, 7 as of 12/10/2010.) 8 BY MR. SAHAM: 9 Q. Could you please take a look at that 10 document, Dr. Geis. 11 MR. SAHAM: And for the record, Plaintiffs' 12 Exhibit 262 is a document bearing Bates numbers 13 DEFS 00754326 through 329. And then the last page 14 of the document, again, indicates that this document 15 was produced from your custodial files, your 16 electronic files. 17 BY MR. SAHAM: 18 Q. Do you have any reason to believe this 19 document wasn't produced from your files? 20 A. I don't recall it either way. 21 Q. Okay. And on the top of the document on 22 the front, it says, For Internal Use Only: Not to 23 be Shown or Given to Any External Audiences - 24 February 9, 2001. Q&amp;A: FDA Advisory Committee</p>



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<p style="text-align: center;">237</p> <p>1 Hearing on Proposed GI Safety Label Revisions for 2 Celebrex. 3 Do you recall there being an advisory 4 committee concerning the proposed GI safety label 5 revisions on February -- on or about February 7th of 6 the year 2001? 7 A. I remember a GI -- FDA GI -- FDA advisory 8 committee meeting taking place. To say it was 9 specifically about proposed GI safety label 10 revisions, I don't know that I can characterize it 11 that way. 12 Q. And -- and -- and when you say it took 13 place, do you recall it taking place on or about 14 February 7th, 2001? 15 A. Yes, I do. 16 Q. Okay. And you recall it was a two-day 17 meeting where both Celebrex and VIOXX were discussed 18 over the 7th and the 8th? Does that comport with 19 your recollection? 20 A. Well, there was one day where Celebrex 21 was discussed. The second day was where the VIOXX 22 was discussed. So it wasn't, like, two days of 23 both. It was one day for one, one day for the 24 other.</p>	<p style="text-align: center;">239</p> <p>1 CLASS trial was complex. It was a big trial. It 2 was a trial that had been conducted -- it was the 3 first of its kind, I think, in the world. 4 So there would be questions about it 5 because it wasn't typical. It wasn't a typical 6 model. Because they asked questions and they 7 discussed it, does that mean they were -- it was 8 difficult? I don't know. 9 Q. Do you recall generally -- 10 MR. HOFF: Whoa, whoa, whoa, wait a second. 11 Did you finish? 12 THE WITNESS: No, I didn't. 13 BY THE WITNESS: 14 A. And I think, once again, we presented all 15 the data and we walked through the process of why we 16 believed the 6-month data was the valid data. 17 BY MR. SAHAM: 18 Q. Are you done now? 19 A. I'm not done now. 20 Q. Sorry, you paused. 21 A. And I think that they were intently 22 looking at it and trying to understand it. Does 23 that mean difficulty or does it mean attention and 24 vigilance to do what they were there to do? I</p>
<p style="text-align: center;">238</p> <p>1 Q. And was there any VIOXX -- or, sorry, was 2 there any Celebrex discussion on the second day, to 3 the extent you remember? 4 A. I don't recall if the advisory committee 5 dis- -- referenced what we had presented the day 6 before during the VIOXX discussion. That, I don't 7 remember. 8 Q. Okay. And looking at the second question 9 here, the Q&amp;A, which I've marked as Exhibit 262, it 10 says, "What was the Arthritis Advisory Committee's 11 recommendation regarding the Celebrex label?" 12 And the answer says, "Due to the 13 complexity of the CLASS data, the advisory panel on 14 day one (February 7) experienced difficulty in 15 interpreting the results." 16 Do you believe that's an accurate 17 statement? 18 A. I don't. 19 Q. Why not? 20 A. I mean, I'm trying to remember -- I mean, 21 when you say the advisory panel experienced 22 difficulty, I don't know what -- in the eyes of 23 whoever wrote this, what difficulty looked like. 24 I mean, I think, as we all know, the</p>	<p style="text-align: center;">240</p> <p>1 wouldn't call it -- I guess I would just wouldn't -- 2 as I recall it, I wouldn't characterize it as 3 difficult. 4 Q. And -- and was it common that the company 5 Pharmacia or Searle generated these types of Q&amp;A 6 to -- to deal with, you know, issues of importance 7 regarding drugs at the company? 8 A. I can't speak to that. 9 Q. I mean -- 10 A. I don't know. 11 Q. -- do you ever remember seeing Qs and As 12 when you worked there? 13 A. There were occasions where, again, 14 they -- there were occasions where the commercial 15 side would put these together, but I don't know if 16 there was a -- it was done systematically, if there 17 was a process or procedure. But on occasion, these 18 types of things, I did see. 19 Q. And -- and you're not disputing that this 20 was found in your electronic files? 21 A. As I said earlier, I don't remember 22 either way. 23 Q. Okay. 24 MR. SAHAM: All right. We -- we need to take a</p>



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<p>241</p> <p>1 break to change the tape, so why don't we take a</p> <p>2 quick -- quick break.</p> <p>3 THE VIDEOGRAPHER: Going off the video record</p> <p>4 at 2:54 p.m.</p> <p>5 This is the end of Tape No. 4.</p> <p>6 (WHEREUPON, a short recess was</p> <p>7 had.)</p> <p>8 THE VIDEOGRAPHER: Going back on the video</p> <p>9 record at 3:05 p.m.</p> <p>10 This is the beginning of Tape No. 5.</p> <p>11 (WHEREUPON, a certain document was</p> <p>12 marked Plaintiffs' Deposition</p> <p>13 Exhibit No. 263, for identification,</p> <p>14 as of 12/10/2010.)</p> <p>15 BY MR. SAHAM:</p> <p>16 Q. Dr. Geis, I'm showing you what's marked</p> <p>17 as Exhibit 263.</p> <p>18 Do you recognize this document?</p> <p>19 A. No, I don't.</p> <p>20 Q. Okay. Does this appear to be a schedule</p> <p>21 that reports shares of stock and options that you</p> <p>22 owned and exercised during the '91 through 2002 time</p> <p>23 period?</p> <p>24 A. Well, it has my name on it. It's a table</p>	<p>243</p> <p>1 how do we want to manage this and you have no plan.</p> <p>2 We got together in early 2000 to work out</p> <p>3 a plan. And as I recall, the -- part of the plan</p> <p>4 was to set a price to exercise some options. And</p> <p>5 when that price was reached, the -- the options -- a</p> <p>6 number of options would be exercised.</p> <p>7 And then I recall, at some point during</p> <p>8 the year, the -- some options were exercised.</p> <p>9 That's what I recall about that.</p> <p>10 Q. Do you recall the name of the wealth</p> <p>11 manager?</p> <p>12 A. The group is currently part of Wachovia.</p> <p>13 I don't know what they were called before, if they</p> <p>14 were -- at one time, they were Kemper. But I don't</p> <p>15 know if they were Kemper -- they were Kemper in the</p> <p>16 year 2000.</p> <p>17 Q. But do you recall the person's name who</p> <p>18 you met with?</p> <p>19 A. Yes, I do.</p> <p>20 Q. What's that person's name?</p> <p>21 A. So the person who is the wealth manager</p> <p>22 is a gentleman named Gary Personette.</p> <p>23 Q. And do you recall the approximate date of</p> <p>24 the meeting?</p>
<p>242</p> <p>1 and it talks about options.</p> <p>2 Q. Well, let me ask you this --</p> <p>3 MR. HOFF: Whoa.</p> <p>4 MR. SAHAM: Sorry, he paused. I thought he was</p> <p>5 done. I'm not doing it on purpose.</p> <p>6 MR. HOFF: Actually, he didn't pause.</p> <p>7 BY THE WITNESS:</p> <p>8 A. It has data, assuming, related to various</p> <p>9 options.</p> <p>10 BY MR. SAHAM:</p> <p>11 Q. Okay. And it says -- it's got your name</p> <p>12 on it, so you don't have any reason to believe this</p> <p>13 isn't outlining your options and option transactions</p> <p>14 in the period specified?</p> <p>15 A. I don't know. I don't -- I don't recall</p> <p>16 this.</p> <p>17 Q. Well -- well, let's do this: Do you</p> <p>18 recall selling about \$3 million worth of Pharmacia</p> <p>19 stock between August and October of the year 2000?</p> <p>20 A. In 2000, wealth managers -- in early</p> <p>21 2000, I had a meeting with my tax guy and my wealth</p> <p>22 managers, and we laid out -- and they were helping</p> <p>23 me lay out a plan for how to manage my assets.</p> <p>24 Because they said, you're getting a lot of assets,</p>	<p>244</p> <p>1 A. It was early in 2000, because we -- I had</p> <p>2 just done the taxes and I knew 2000 was going to be</p> <p>3 a very busy year with the two NDAs and two SNDAs.</p> <p>4 And they said, let's get together early and lay out</p> <p>5 a plan.</p> <p>6 Q. And do you know how to spell Personette?</p> <p>7 A. P-e-r-s-o-n-e-t-t-e, I think.</p> <p>8 Q. Okay. And you sold -- as a result, you</p> <p>9 exercised and then sold approximately 75,000 shares</p> <p>10 of Pharmacia stock for proceeds of over \$3 million;</p> <p>11 is that correct, sir?</p> <p>12 A. I don't know if that's correct.</p> <p>13 Q. Well, let me ask you this: In any year</p> <p>14 other than three -- other than the year 2000, did</p> <p>15 you ever sell \$3 million worth of stock before?</p> <p>16 A. I exercised stock options before 2000. I</p> <p>17 don't know how much they would have -- I don't know</p> <p>18 what the word you're using. I don't know -- you</p> <p>19 know, I don't know the specifics around it, but I do</p> <p>20 know I exercised stock options before 2000.</p> <p>21 Q. Well, do you know what your</p> <p>22 approximate --</p> <p>23 MR. HOFF: Are you getting that \$3 million from</p> <p>24 this chart (indicating)?</p>



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<p style="text-align: center;">245</p> <p>1 MR. SAHAM: Yeah. I'm looking at the second --</p> <p>2 the -- the shares that were exercised, the 75,000</p> <p>3 shares that were exercised, the number of options --</p> <p>4 MR. HOFF: And you're multiplying --</p> <p>5 MR. SAHAM: -- in the year 2000.</p> <p>6 MR. HOFF: -- it by the dollar amount there?</p> <p>7 MR. SAHAM: Yeah, of all those dollar amounts,</p> <p>8 and it's about 3.7 million.</p> <p>9 MR. HOFF: I just wanted it to be clear --</p> <p>10 BY MR. SAHAM:</p> <p>11 Q. And I don't want to get into your, like,</p> <p>12 personal business, you know, but --</p> <p>13 A. Sure.</p> <p>14 Q. -- in the year 2000, what was your net</p> <p>15 worth, approximately? I mean, was 3 million a lot</p> <p>16 for you back then --</p> <p>17 MR. HOFF: I'll object --</p> <p>18 BY MR. SAHAM:</p> <p>19 Q. -- or was that just a little bit?</p> <p>20 MR. HOFF: -- to the form of the question,</p> <p>21 unless you're saying, in the abstract, is 3 million</p> <p>22 a lot of money, you know.</p> <p>23 BY MR. SAHAM:</p> <p>24 Q. I'm just asking you --</p>	<p style="text-align: center;">247</p> <p>1 A. Okay. In 2000? Or before 2000? Okay.</p> <p>2 I have a house. I don't know what it was worth in</p> <p>3 2000. It's in Lincoln Park, which is -- the real</p> <p>4 estate is pretty good in Lincoln Park, so that may</p> <p>5 have been worth 2 million, I guess. I don't know.</p> <p>6 And then what I had saved.</p> <p>7 Q. Okay. So would you say your net worth</p> <p>8 was less than 3 million, other than this stock, your</p> <p>9 other assets?</p> <p>10 See, I asked a bad question.</p> <p>11 Were your other assets, other than this</p> <p>12 Pharmacia stock, the 75,000 shares that you</p> <p>13 exercised in 2000, would you say your net worth</p> <p>14 other than that was -- was some amount less than</p> <p>15 3 million?</p> <p>16 MR. HOFF: Objection to form.</p> <p>17 BY THE WITNESS:</p> <p>18 A. Yeah. So first of all, you said that I</p> <p>19 exercised 3 million worth of stock, and I don't</p> <p>20 remember doing that, so I want to make that clear.</p> <p>21 So before the year 2000, I think it's</p> <p>22 safe to say my net worth was under 3 million.</p> <p>23 BY MR. SAHAM:</p> <p>24 Q. Okay. So we're looking here -- and I</p>
<p style="text-align: center;">246</p> <p>1 MR. HOFF: We haven't established that</p> <p>2 3 million is the right number.</p> <p>3 BY MR. SAHAM:</p> <p>4 Q. Well, what was your -- what was your net</p> <p>5 worth, to the extent you remember? And -- and it</p> <p>6 can be very -- you know, it doesn't have to be</p> <p>7 exact.</p> <p>8 But what was your net worth in 2000?</p> <p>9 A. I don't know -- how do you figure net</p> <p>10 worth? I mean, is it -- like, do you say, how much</p> <p>11 money in the bank? How much is your house worth?</p> <p>12 How much is your car worth?</p> <p>13 Q. Okay.</p> <p>14 A. I mean, what do you --</p> <p>15 Q. You can do that however you want.</p> <p>16 A. I don't know.</p> <p>17 Q. Just give me a ballpark figure.</p> <p>18 A. Wow. I mean, I was putting the maximum</p> <p>19 amount that I could into the -- the retirement fund.</p> <p>20 I don't even remember what my salary was.</p> <p>21 Q. Well, I'll show you a document that shows</p> <p>22 you that soon.</p> <p>23 A. Okay.</p> <p>24 Q. It was about \$250,000 a year.</p>	<p style="text-align: center;">248</p> <p>1 just want to walk you through this document that</p> <p>2 I've marked as Exhibit 263. And it has your name on</p> <p>3 it.</p> <p>4 And it says down there in the bottom --</p> <p>5 the bottom part of the chart, it says Number of</p> <p>6 Options. And then if you total them all up, it says</p> <p>7 75,540.</p> <p>8 Are you with me?</p> <p>9 A. I am.</p> <p>10 Q. So does that mean you had -- or -- or --</p> <p>11 and this -- and this is -- the first column says,</p> <p>12 Activity Date. It's labeled Option Activity. You</p> <p>13 see me? And it says Activity Date, and it lists,</p> <p>14 you know, some dates, several -- several</p> <p>15 transactions that occurred on 10/2/2000.</p> <p>16 Do you see that?</p> <p>17 A. Yes, I do.</p> <p>18 Q. And then it also lists --</p> <p>19 A. Right.</p> <p>20 Q. -- two transactions on 9/29 --</p> <p>21 A. Right.</p> <p>22 Q. -- 2000?</p> <p>23 A. Yes.</p> <p>24 Q. And then it lists one transaction on</p>



<p>249</p> <p>1 8/16/2000. And then it lists the activity. It says</p> <p>2 Cash, then it says Grant Type/Grant Code. And It</p> <p>3 says PHAM NQC. And then the next column lists the</p> <p>4 number of options.</p> <p>5 A. Yes.</p> <p>6 Q. If you tally all those up, it equals</p> <p>7 75,540.</p> <p>8 Do you see that?</p> <p>9 A. I do.</p> <p>10 Q. And then there's the Grant Date. And I</p> <p>11 assume that's the date those options were granted.</p> <p>12 Does that make sense?</p> <p>13 A. As much as I understand that, yes.</p> <p>14 Q. And then it has the Exercise Price.</p> <p>15 Is that your understanding, the exercise</p> <p>16 price on the option? That's what you can actually</p> <p>17 sell it for?</p> <p>18 A. No, I don't understand what that means.</p> <p>19 Q. Isn't -- isn't that -- you get an -- if</p> <p>20 you get a stock option, you might be able to buy it</p> <p>21 for 9, but if the stock's trading at 40 at the time,</p> <p>22 if you exercise the option, you're going to make</p> <p>23 some profit because you're only paying 9 of the --</p> <p>24 A. Right.</p>	<p>251</p> <p>1 and just keep that in front of you. We're --</p> <p>2 THE WITNESS: Okay.</p> <p>3 MR. SAHAM: It's the same thing, it's just a --</p> <p>4 an idiosyncrasy in the way that the document was</p> <p>5 produced to me last night that I want to make clear</p> <p>6 for everyone.</p> <p>7 (WHEREUPON, a certain document was</p> <p>8 marked Plaintiffs' Deposition</p> <p>9 Exhibit No. 264, for identification,</p> <p>10 as of 12/10/2010.)</p> <p>11 MR. SAHAM: So I'm marking this document which</p> <p>12 bears the Bates number DEFS 001958. Showing this</p> <p>13 document to you, which appears to be the same</p> <p>14 document, but -- that I've marked as 263. But part</p> <p>15 of it's cut off.</p> <p>16 MR. HOFF: Actually, it's not the same, but</p> <p>17 that's okay.</p> <p>18 MR. SAHAM: Well -- but in any event, you guys</p> <p>19 produced to me 2 -- what I've marked as 264?</p> <p>20 MR. HOFF: That's true.</p> <p>21 MR. SAHAM: And then last night, you sent me a</p> <p>22 document, and I'll represent to you it's this</p> <p>23 document that's 263.</p> <p>24 MR. HOFF: Uh-huh.</p>
<p>250</p> <p>1 Q. -- what it was granted at and stay solid</p> <p>2 at 40?</p> <p>3 A. So is that, the exercise price, the price</p> <p>4 that is the price of the stock the day you exercise?</p> <p>5 So is that what that --</p> <p>6 Q. I think --</p> <p>7 A. -- means?</p> <p>8 Q. -- that's what it indicates to me,</p> <p>9 anyway.</p> <p>10 Is it logical to you that that's what it</p> <p>11 means?</p> <p>12 MR. HOFF: Well, objection.</p> <p>13 MR. SAHAM: We can stipulate, too, if you want,</p> <p>14 John.</p> <p>15 MR. HOFF: I -- no, no. I'm not going to</p> <p>16 stipulate. I think you should just ask him if he --</p> <p>17 you know, what -- what he knows about the document</p> <p>18 and what he can tell you about it.</p> <p>19 MR. SAHAM: Okay. Well, I mean, I'm just --</p> <p>20 MR. HOFF: This is a -- this is a company</p> <p>21 document.</p> <p>22 MR. SAHAM: Yes. And -- and I -- maybe I</p> <p>23 should make this statement on the record. And I'm</p> <p>24 going to -- let me mark as Exhibit 264, as well --</p>	<p>252</p> <p>1 MR. SAHAM: And it has a Bates number on it</p> <p>2 when I opened it up electronically, but when I print</p> <p>3 it out, for some reason the Bates number does not</p> <p>4 print out.</p> <p>5 MR. HOFF: Okay.</p> <p>6 MR. SAHAM: And, you know, I -- I'd like there</p> <p>7 to be some understanding between us, you know, that</p> <p>8 you guys look at this document and determine it's</p> <p>9 what you produced. But the Bates number for some</p> <p>10 reason does not print.</p> <p>11 MR. HOFF: Well, let's --</p> <p>12 MR. WEISS: You -- you wouldn't have it unless</p> <p>13 I produced it to you.</p> <p>14 MR. SAHAM: Right. So -- and that's all I'm</p> <p>15 getting at.</p> <p>16 MR. HOFF: I'm -- I'm -- this looks like what</p> <p>17 we gave you most recently. That would be</p> <p>18 Exhibit 263. The earlier document is -- I think</p> <p>19 you're marking 264.</p> <p>20 MR. SAHAM: That's what you provided me about a</p> <p>21 week ago?</p> <p>22 MR. HOFF: Correct.</p> <p>23 MR. SAHAM: And then 263 is what you provided</p> <p>24 me last night?</p>



<p style="text-align: center;">253</p> <p>1 MR. HOFF: Was it last night?</p> <p>2 MR. WEISS: Yeah.</p> <p>3 MR. HOFF: Correct, yeah.</p> <p>4 BY MR. SAHAM:</p> <p>5 Q. So looking back at 263, sir, you know,</p> <p>6 what I did to come up with that 3 million in</p> <p>7 proceeds is, I just multiplied all the exercise</p> <p>8 prices, you know, by the -- by the number of options</p> <p>9 that were exercised at that price. And I'm not</p> <p>10 great at math, but I get something over \$3 million.</p> <p>11 MR. WEISS: Could you say -- can you read that</p> <p>12 back.</p> <p>13 MR. SAHAM: Well, I'll say it again.</p> <p>14 BY MR. SAHAM:</p> <p>15 Q. Well, I'm just saying that you've got</p> <p>16 these number of options which are exercised on</p> <p>17 particular days, and then you have an exercise</p> <p>18 price.</p> <p>19 So -- and then you -- and you don't have</p> <p>20 a total for the exercise price or -- or for the</p> <p>21 total amount. But what I did is I multiplied the</p> <p>22 number of shares in each spot times the -- the price</p> <p>23 and then added them all together and I get something</p> <p>24 around \$3 million.</p>	<p style="text-align: center;">255</p> <p>1 together a game plan.</p> <p>2 2000, I knew, was going to be a very busy</p> <p>3 year for me because I was scheduled to submit or</p> <p>4 oversee the team that was submitting two NDAs and</p> <p>5 two SNDAs. So the idea was, if we are going to get</p> <p>6 together and put a plan together, it has to be early</p> <p>7 in the year.</p> <p>8 I do remember we got together. We talked</p> <p>9 about a plan. And -- and -- and one of the --</p> <p>10 the -- the -- the plans was to, let's exercise some</p> <p>11 stock options if it is possible and if it is</p> <p>12 appropriate. And that was part of the plan.</p> <p>13 And then I do remember, later, hearing</p> <p>14 that they did exercise them, but I don't remember</p> <p>15 amounts, numbers or anything like that.</p> <p>16 Q. Now, do you remember -- and I know you</p> <p>17 don't -- you just testified you don't remember the</p> <p>18 exact amounts, but do you remember selling in the</p> <p>19 millions of dollars worth of stock -- Pharmacia</p> <p>20 stock in the year 2000?</p> <p>21 A. I don't.</p> <p>22 Q. You have no recollection of whether it</p> <p>23 was \$38 worth of stock or a lot?</p> <p>24 A. I knew it was a lot. I don't know how</p>
<p style="text-align: center;">254</p> <p>1 MR. WEISS: But you --</p> <p>2 BY MR. SAHAM:</p> <p>3 Q. Is that illogical to you to calculate</p> <p>4 what this document is saying, sir?</p> <p>5 A. I'm not a stock person, so I don't</p> <p>6 understand this. But what you say is not -- it's</p> <p>7 not nonsensical.</p> <p>8 Q. Okay.</p> <p>9 A. I just don't know if you're accurate.</p> <p>10 Q. Right. And then what I'm getting at,</p> <p>11 too, is that you're a guy that was worth less than</p> <p>12 \$3 million in 2000. If you sold \$3 million worth of</p> <p>13 stock, don't -- don't you think you'd remember?</p> <p>14 Isn't that sort of a big deal?</p> <p>15 A. Well, what I remember, as I said, was</p> <p>16 meeting with the tax fella. So at a time of my</p> <p>17 life, whatever year 2000 was -- so I'm getting close</p> <p>18 to 50 -- the tax guy is doing my taxes for 1999 and</p> <p>19 says, you know, you have a lot of assets. We need</p> <p>20 to put a plan together for you because -- or do you</p> <p>21 have a plan for -- for the rest of your life?</p> <p>22 And I said, yeah, the plan is, work and</p> <p>23 put the money in the bank. And he says, well, let's</p> <p>24 get together with these wealth managers and put</p>	<p style="text-align: center;">256</p> <p>1 much it was -- it was.</p> <p>2 Q. Okay. And what did you do with the</p> <p>3 proceeds?</p> <p>4 A. The proceeds, I -- the wealth managers</p> <p>5 created an annuity at some point, whether it was</p> <p>6 right away or not.</p> <p>7 Q. And --</p> <p>8 A. Part of the -- part of the proceeds went</p> <p>9 to an annuity, and I don't know exactly what the</p> <p>10 other went to.</p> <p>11 Q. Okay. And do you still have the annuity?</p> <p>12 A. Not that particular annuity, no.</p> <p>13 Q. Did you sort of roll it over into</p> <p>14 something else?</p> <p>15 A. As I recall, yes, that's what we did.</p> <p>16 Q. And what's the size of that annuity --</p> <p>17 A. In terms of --</p> <p>18 Q. -- the value?</p> <p>19 A. -- what it's worth?</p> <p>20 Q. Correct.</p> <p>21 A. So I -- well, it depends on what you</p> <p>22 mean, "what it's worth." Because the -- if I sold</p> <p>23 it today, I think it's different than if I wait.</p> <p>24 And I guess you take money out of it when you get so</p>



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<p style="text-align: center;">257</p> <p>1 old, something like that. Is that -- isn't that how 2 that works?</p> <p>3 But anyway, I think the last time I met 4 with the wealth managers, which is now a different 5 group of people, I think -- I think it was, like, a 6 million dollars, a million two.</p> <p>7 Q. Okay. And then when you look at the 8 exercise price for each of these shares that we were 9 looking at at that middle column, that number is 10 greater than the option price for each of these 11 entries, each of these -- one, two, three, four, 12 five, six, seven -- eight entries that are listed in 13 this table, correct?</p> <p>14 A. That's correct.</p> <p>15 Q. And the difference between the option 16 price and the exercise price, that's profit for 17 yourself, correct, sir?</p> <p>18 MR. HOFF: Well, objection to form.</p> <p>19 BY MR. SAHAM:</p> <p>20 Q. Uncle Sam might take some, but the rest 21 is profit, correct?</p> <p>22 MR. HOFF: Objection to form.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Well, as you're doing the math and what I</p>	<p style="text-align: center;">259</p> <p>1 A. I --</p> <p>2 Q. And then you add them together 3 cumulatively, and I get 1.6 million.</p> <p>4 A. You're adding exercise gain per option 5 and getting 1.6 million?</p> <p>6 Q. Yeah.</p> <p>7 A. Is that what you're doing?</p> <p>8 Q. You have to multiply the exercise gain 9 for each of those number of shares by the number of 10 options.</p> <p>11 A. I can't do that in my head and come up 12 with a number.</p> <p>13 Q. Okay. But does it look to be a 14 significant number, a number in excess of a million 15 dollars, by eyeballing it?</p> <p>16 MR. HOFF: Objection to form.</p> <p>17 BY THE WITNESS:</p> <p>18 A. So that would be 2 -- well, it looks like 19 it could be over a million.</p> <p>20 BY MR. SAHAM:</p> <p>21 Q. Okay. And then other than your meeting 22 with the wealth manager, is there any other reason 23 you decided to exercise this stock -- these stock 24 options in the year 2000?</p>
<p style="text-align: center;">258</p> <p>1 know of these things, that is -- that is what they 2 call the exercise gain. Whether it's profit to me 3 doesn't -- I don't know exactly if that means it's 4 profit to me or not.</p> <p>5 BY MR. SAHAM:</p> <p>6 Q. And if you do that math there, the profit 7 or the exercise gain is over \$1.6 million, isn't it?</p> <p>8 A. I don't know. I haven't added it.</p> <p>9 Q. You're not disputing that it looks 10 about -- to be about \$1.6 million, though, are you, 11 sir?</p> <p>12 MR. HOFF: Objection to form.</p> <p>13 BY THE WITNESS:</p> <p>14 A. Well, help me. Help me with this. Where 15 am I supposed to look?</p> <p>16 BY MR. SAHAM:</p> <p>17 Q. Well, I'm just looking at the --</p> <p>18 A. So you --</p> <p>19 Q. -- difference between the option price --</p> <p>20 A. Right.</p> <p>21 Q. -- and the exercise price. And that 22 difference multiplied by the number of options would 23 be the -- you called it the exercise gain and I call 24 it profit, on those particular shares.</p>	<p style="text-align: center;">260</p> <p>1 A. No.</p> <p>2 Q. And do you know, out of -- you -- you 3 exercised 75,540 options, and in the table above, 4 some of the options weren't -- weren't given to you, 5 even the option, until after 2000.</p> <p>6 So out of the ones prior to 2000, do you 7 know which of those or what percentage or how 8 many -- I'm -- I'm sorry, let me ask the question 9 better.</p> <p>10 You exercised 75,000 options during 2000.</p> <p>11 Do you know how many options during the 12 year 2000 you had available to you to exercise?</p> <p>13 MR. HOFF: Objection --</p> <p>14 BY MR. SAHAM:</p> <p>15 Q. Whether it was more than 75,000 options 16 or not -- shares?</p> <p>17 MR. HOFF: Objection, form.</p> <p>18 BY THE WITNESS:</p> <p>19 A. So I just want to get this straight. So 20 that there could have been options that were 21 available to exercise and I didn't exercise them 22 all, you're suggesting --</p> <p>23 BY MR. SAHAM:</p> <p>24 Q. Yeah. I'm asking you whether you exer- -</p>



<p>261</p> <p>1 whether you know if you exercised all of them or 2 not?</p> <p>3 A. I know -- as I recall -- and, again, I 4 don't remember the details of what this was. As I 5 recall, we did not exercise them all.</p> <p>6 Q. Do you know what percentage you 7 exercised?</p> <p>8 A. I don't.</p> <p>9 Q. Do you know, would you have records or 10 documents that would show that information?</p> <p>11 A. I've looked through my documents and do 12 not have any records of -- of this, other than -- 13 other than tax returns.</p> <p>14 MR. SAHAM: Okay. And we -- we make a request 15 formally for those documents to the extent they're 16 in Mr. -- or Dr. Geis's possession or the company's 17 possession, that a document be produced to us and 18 that certainly we could serve you with an 19 interrogatory, as well.</p> <p>20 But to the extent there is a document 21 that indicates how many or documents together that 22 indicate how many options were available or had 23 vested in this point in time during 2000, we would 24 like to have them produced.</p>	<p>263</p> <p>1 Re: Deviation from SOP for above-referenced studies 2 (CLASS trial).</p> <p>3 BY MR. SAHAM:</p> <p>4 Q. I'd ask you if you recognize this 5 document?</p> <p>6 A. I don't recall seeing this.</p> <p>7 Q. But this is an e-mail that you would 8 have -- or that you sent on March 17, 2000, to 9 Dr. Friedman?</p> <p>10 A. I don't recall seeing it, but I don't -- 11 I don't recall either way.</p> <p>12 Q. And this is a memo that was written to 13 the file that your name's on as a From, on the 14 second page?</p> <p>15 A. This is -- it's a memo, and my name's 16 typed on it. So in that sense, yes.</p> <p>17 Q. And the second paragraph on the second 18 page states, "Notification of database closure will 19 be restricted to a limited subset of the Study Team 20 to minimize the potential dissemination of 21 information that might violate SEC regulations 22 regarding disclosure of material information." 23 Do you see that?</p> <p>24 A. I do see that.</p>
<p>262</p> <p>1 MR. HOFF: We'll consider it. I'll just say, 2 we have been trying to find the documents that 3 reflect the stock activity, and so far, the best we 4 could come up with is what we've given to you.</p> <p>5 MR. SAHAM: Thank you.</p> <p>6 MR. HOFF: But we'll -- we'll continue.</p> <p>7 MR. SAHAM: Okay. I want to show you what I'm 8 marking as Plaintiffs' Exhibit 265.</p> <p>9 (WHEREUPON, a certain document was 10 marked Plaintiffs' Deposition 11 Exhibit No. 265, for identification, 12 as of 12/10/2010.)</p> <p>13 BY MR. SAHAM:</p> <p>14 Q. Could you please take a look at 15 Plaintiffs' Exhibit 265.</p> <p>16 MR. SAHAM: And for the record, Plaintiffs' 17 Exhibit 265 is a two-page document bearing 18 Bates numbers DEFS 01605472 through 73. The first 19 page is an e-mail from George S. Geis to Michael 20 Friedman, dated March 17, 2000. The subject is 21 CLASS Database Close. And the attachment, or the 22 second page of the document, is dated 17 March 2000 23 to study file N49-98-02-035 and 102, and it's from 24 Jay Lefkowitz, W. Zhao and G. Steven Geis. And it's</p>	<p>264</p> <p>1 Q. And did you have an understanding in 2 March of 2000 that there was, at least for some 3 point in time, a restriction on trading stock 4 because of the -- the results of the CLASS trial 5 were known internally but not externally to the 6 public?</p> <p>7 MR. HOFF: Objection to form.</p> <p>8 BY THE WITNESS:</p> <p>9 A. Could you repeat the question?</p> <p>10 MR. SAHAM: Could you read that back, ma'am. 11 (WHEREUPON, the record was read by 12 the reporter.)</p> <p>13 BY THE WITNESS:</p> <p>14 A. I did not know of that.</p> <p>15 BY MR. SAHAM:</p> <p>16 Q. But this document seems to be indicating 17 that the database -- or strike that.</p> <p>18 This document does indicate that, quote, 19 notification of database closure will be restricted 20 to a limited subset of the Study Team to minimize 21 the potential dissemination of information that 22 might violate SEC regulations regarding disclosure 23 of material information. 24 That's what the document says, correct?</p>



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<p>265</p> <p>1 MR. HOFF: Well, why don't you finish the rest</p> <p>2 of the paragraph?</p> <p>3 BY THE WITNESS:</p> <p>4 A. So the -- the rest of the paragraph is,</p> <p>5 "This period of restriction will be limited to the</p> <p>6 period of time up to approval of the pending merger</p> <p>7 between Pharmacia/Upjohn and Monsanto."</p> <p>8 So it says to me, this is -- this SEC</p> <p>9 regulation is with respect to the merger --</p> <p>10 BY MR. SAHAM:</p> <p>11 Q. Did you also --</p> <p>12 A. -- not about having anything to do with</p> <p>13 trading stock related to CLASS.</p> <p>14 Q. Would -- would you agree that there was</p> <p>15 material information that was in the possession of</p> <p>16 yourself and others internally at Pharmacia after</p> <p>17 the merger before it was disclosed publicly?</p> <p>18 MR. HOFF: Object to the form of the question.</p> <p>19 BY MR. SAHAM:</p> <p>20 Q. With respect to the CLASS data.</p> <p>21 A. Could you repeat the question?</p> <p>22 Q. Okay. Was there information that you</p> <p>23 knew internally -- because you were working on the</p> <p>24 study -- and let's say at least prior to April 17th</p>	<p>267</p> <p>1 Silverstein did acknowledge there was data beyond</p> <p>2 six months. But we believed the data, the 6-month</p> <p>3 data was valid.</p> <p>4 That was presented again at DDW in</p> <p>5 April -- excuse me -- in May. After Fred</p> <p>6 Silverstein's presentation, the analyst wrote</p> <p>7 analyst reports acknowledging there was data beyond</p> <p>8 the six months, so that was in the public.</p> <p>9 And Merck, in their presentation at DDW</p> <p>10 in May of 2000, also acknowledged there was data</p> <p>11 beyond six months.</p> <p>12 So the public knew there was data beyond</p> <p>13 six months through a variety of venues from April,</p> <p>14 whenever American College of Physicians took place,</p> <p>15 onward.</p> <p>16 BY MR. SAHAM:</p> <p>17 Q. Did any of those communications at any of</p> <p>18 those venues inform the public that the data after</p> <p>19 six months was less favorable to Celebrex than the</p> <p>20 6-month data, at least on certain endpoints?</p> <p>21 A. It was -- they were -- it was</p> <p>22 acknowledged that it was invalid data. So to call</p> <p>23 it less favorable is inaccurate because if it's</p> <p>24 invalid, any comparison is meaningless.</p>
<p>266</p> <p>1 when there was some disclosure about it -- prior to</p> <p>2 that time, you knew some stuff that people on the</p> <p>3 street didn't know about CLASS, correct?</p> <p>4 MR. HOFF: Objection to form.</p> <p>5 BY THE WITNESS:</p> <p>6 A. So prior to Fred Silverstein's</p> <p>7 presentation, we had the results of the trial. In</p> <p>8 that sense -- and that was not publicly available.</p> <p>9 BY MR. SAHAM:</p> <p>10 Q. And even after April 17th, there was some</p> <p>11 stuff that you knew that the rest of the public</p> <p>12 didn't know, right?</p> <p>13 MR. HOFF: Objection to form.</p> <p>14 BY THE WITNESS:</p> <p>15 A. What do you mean "there was some stuff"?</p> <p>16 BY MR. SAHAM:</p> <p>17 Q. Well, you knew that the -- the rest of</p> <p>18 the data wasn't being included because you thought</p> <p>19 it was invalid, and, you know, "Joe Q. public"</p> <p>20 didn't know that necessarily?</p> <p>21 A. Well --</p> <p>22 MR. HOFF: Objection to form.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Well, no, that's not true, because Fred</p>	<p>268</p> <p>1 Q. But certainly nobody was told that --</p> <p>2 invalid, not invalid, that statistically significant</p> <p>3 comparison that's in Figure 2B in your JAMA article,</p> <p>4 nobody was told that that comparison mathematically,</p> <p>5 statistically, didn't hold for the entire study</p> <p>6 period; is that correct, sir?</p> <p>7 A. So, again, it was invalid data and</p> <p>8 P Values related to invalid data were not -- were</p> <p>9 not talked about. However, all the data was</p> <p>10 submitted to the FDA in June and was fully vetted in</p> <p>11 the February advisory committee meeting.</p> <p>12 Q. And the FDA did not make that data</p> <p>13 public, that full data, until February of 2001; is</p> <p>14 that correct, sir?</p> <p>15 A. I don't know for sure.</p> <p>16 Q. Okay. But you don't -- you're not</p> <p>17 disputing that fact because you don't know?</p> <p>18 A. I don't know either way.</p> <p>19 Q. Okay. I want to show you what I'm</p> <p>20 marking as Plaintiffs' Exhibit 266.</p> <p>21 (WHEREUPON, a certain document was</p> <p>22 marked Plaintiffs' Deposition</p> <p>23 Exhibit No. 266, for identification,</p> <p>24 as of 12/10/2010.)</p>



<p>269</p> <p>1 BY MR. SAHAM:</p> <p>2 Q. Could you please take a look at</p> <p>3 Plaintiffs' Exhibit 266.</p> <p>4 And I just ask you, does this document</p> <p>5 appear to be a spreadsheet entry describing your</p> <p>6 compensation in the 1999 through 2002 time frame?</p> <p>7 A. I don't know what this is. I've never</p> <p>8 seen this before, so I -- so I don't know.</p> <p>9 Q. Well, it's got your name on it, right?</p> <p>10 It says Geis, G.S.?</p> <p>11 A. Yes.</p> <p>12 Q. And then it lists -- and I'm looking at</p> <p>13 lines 10 through 23 for 2000. It says you got an</p> <p>14 Edgar M. Queeny award and they gave you 40 grand; is</p> <p>15 that right?</p> <p>16 A. That sounds familiar.</p> <p>17 Q. So that does sound familiar.</p> <p>18 And then it says, 2000 Annual Incentive</p> <p>19 Award-Pension-SIP able. It says 264 and some</p> <p>20 change?</p> <p>21 A. That, I don't know what that means.</p> <p>22 Q. And then it says -- but that looks to be</p> <p>23 like a \$264,000?</p> <p>24 A. Well, the number is 264, but I don't know</p>	<p>271</p> <p>1 A. Well, I -- I'm confident I've never seen</p> <p>2 this document before.</p> <p>3 Q. And do you recall approximately what your</p> <p>4 total compensation was from Pharmacia in, you</p> <p>5 know -- if -- you got tax returns from 2000, right?</p> <p>6 A. I did.</p> <p>7 Q. Do you still have them?</p> <p>8 A. I do.</p> <p>9 Q. Would you mind giving them to your</p> <p>10 lawyers to produce?</p> <p>11 A. Sure.</p> <p>12 Q. Okay. I'd appreciate it if you could do</p> <p>13 that, because then we'd be able to, I think,</p> <p>14 definitively answer how much you were compensated</p> <p>15 that year.</p> <p>16 MR. HOFF: Well, we'll consider --</p> <p>17 MR. SAHAM: Okay.</p> <p>18 MR. HOFF: -- what --</p> <p>19 MR. SAHAM: And if you want to redact Social</p> <p>20 Security -- Social Security numbers, I'm all right</p> <p>21 with that.</p> <p>22 MR. HOFF: Well, we'll take a look at them and</p> <p>23 get back to you.</p> <p>24 MR. SAHAM: I'd appreciate that, John. Thank</p>
<p>270</p> <p>1 what Annual Incentive Award-Pen-SIP means.</p> <p>2 Q. And then you drop down to Block 13. It</p> <p>3 says 2000 Restricted Stock Deferral, 318,000.</p> <p>4 Do you see that?</p> <p>5 A. I see that.</p> <p>6 Q. Okay. And then under that, there's stock</p> <p>7 options listed, 2 through 7. And if you add those</p> <p>8 all up -- one's 269,000; one's 147,000; one's</p> <p>9 169,000; one's 133,000; one's 344,000; and one's</p> <p>10 278,000.</p> <p>11 Do you think that seems like it may</p> <p>12 correspond with the numbers we had looked at that --</p> <p>13 the 3 million and the 1.6 million in the -- that we</p> <p>14 looked at in Exhibit 263 and 264?</p> <p>15 A. I -- I don't know what this is referring</p> <p>16 to.</p> <p>17 Q. And then it says, Regular Pay \$248,000.</p> <p>18 Does that seem consistent with what you</p> <p>19 were being paid in this time frame as an</p> <p>20 executive -- or as a vice president?</p> <p>21 A. It sounds like it's within the range.</p> <p>22 Q. And you just don't recognize this</p> <p>23 document? You can't dispute it or confirm what it</p> <p>24 is?</p>	<p>272</p> <p>1 you.</p> <p>2 I want to show you what I'm marking as</p> <p>3 Plaintiffs' Exhibit 267.</p> <p>4 (WHEREUPON, a certain document was</p> <p>5 marked Plaintiffs' Deposition</p> <p>6 Exhibit No. 267, for identification,</p> <p>7 as of 12/10/2010.)</p> <p>8 MR. SAHAM: Could you please take a look at</p> <p>9 Exhibit 267. And for the record, Exhibit 267 is a</p> <p>10 two page e-mail chain, Bates numbers DEFS 00029529</p> <p>11 through 530.</p> <p>12 BY MR. SAHAM:</p> <p>13 Q. And you're not on this chain, but what</p> <p>14 I'm referring to -- well, no, you are. It -- it --</p> <p>15 it -- the subject matter of the e-mail at the bottom</p> <p>16 of the first page from Fletcher to Weiner, it says,</p> <p>17 Background on request for Joe Feczko to call G.</p> <p>18 Steven Geis.</p> <p>19 And then it refers, on the next page,</p> <p>20 that you're basically giving a consultant agreement</p> <p>21 when you left Pfizer that could pay you up to</p> <p>22 \$350,000 for that year to talk about CLASS and deal</p> <p>23 with CLASS and Celebrex issues; is that right?</p> <p>24 A. Wait a second. I -- I need to look at</p>



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<p>273</p> <p>1 this and read it and see what it is.</p> <p>2 So what's the question?</p> <p>3 Q. Well, my question is, do you recall</p> <p>4 getting a consulting agreement when you left Pfizer</p> <p>5 in -- I guess, 2003, did you leave Pfizer?</p> <p>6 A. So I was never an employee of Pfizer.</p> <p>7 Pharmacia/Monsanto merger was in 2000. I retired in</p> <p>8 August of 2002. It was still Pharmacia. When I</p> <p>9 left Pharmacia, Pharmacia asked me to consult</p> <p>10 related to helping with the arbitration issues for</p> <p>11 the Cox-lls and those types of things.</p> <p>12 So I had a consulting agreement with</p> <p>13 Pharmacia, and then I believe it was in 2000 -- was</p> <p>14 it in 2002 that Pfizer bought Pharmacia? I don't</p> <p>15 recall that we ended up with a contract -- I ended</p> <p>16 up, then, with a contract with Pfizer, but I can't</p> <p>17 remember.</p> <p>18 Q. And what arbitration issues are you</p> <p>19 referring to?</p> <p>20 A. The -- well, I don't know exactly what</p> <p>21 they're referring to here. But -- but arbitration</p> <p>22 with European authorities refers to when you make a</p> <p>23 submission to the European Union Community of --</p> <p>24 of -- of Countries like you do to the FDA.</p>	<p>275</p> <p>1 A. Well, I think it was -- it was a one-year</p> <p>2 contract that started around August or September</p> <p>3 of 2002 with Pharmacia to end, if it would be a</p> <p>4 year, in August or September of 2003. But then</p> <p>5 Pfizer bought Pharmacia, and what I don't remember</p> <p>6 is if there was a new contract written with Pfizer.</p> <p>7 Q. When was the last time you received</p> <p>8 consulting money from either Pharmacia or Pfizer?</p> <p>9 A. My best recollection is sometime in 2002.</p> <p>10 Q. Okay. And then what about the depos you</p> <p>11 gave in 2008, did they pay you to appear at those</p> <p>12 depos -- depositions?</p> <p>13 A. For -- for prep time, I was -- I wasn't</p> <p>14 paid by the company. I believe I was -- I was</p> <p>15 compensated for my time through -- I don't know if</p> <p>16 it was Sidley or through the other -- another law</p> <p>17 firm.</p> <p>18 Q. And Sidley &amp; Austin, the law firm that</p> <p>19 we're at today?</p> <p>20 A. Yes.</p> <p>21 Q. And -- and is it your understanding that</p> <p>22 Pfizer would have reimbursed Sidley for paying you,</p> <p>23 or do you think they were just paying you</p> <p>24 themselves?</p>
<p>274</p> <p>1 There is a process that you go through</p> <p>2 where you -- where you review the data, answer</p> <p>3 questions to the data. And my understanding is the</p> <p>4 term is called arbitration. So it's the interaction</p> <p>5 with the Health Ministries in Europe regarding your</p> <p>6 submission.</p> <p>7 Q. Okay. And then at any point in time, did</p> <p>8 you become a paid consultant of Pfizer?</p> <p>9 A. I don't recall. As I recall, there was a</p> <p>10 consulting agreement with Pharmacia that went for a</p> <p>11 year, and I don't think there was another one with</p> <p>12 Pfizer.</p> <p>13 Q. Have -- have you ever been paid by either</p> <p>14 Pharmacia or Pfizer after 2002 or 2003?</p> <p>15 A. Well, in -- so in 2002 -- so it was</p> <p>16 August 2002 when I retired, and then during 2002, I</p> <p>17 was consulting for -- for Pharmacia and was -- and</p> <p>18 did get consulting fees as a result.</p> <p>19 Q. I'm talking about after that.</p> <p>20 Did you ever get paid by either Pharmacia</p> <p>21 or Pfizer after that?</p> <p>22 A. After all the consulting? After the</p> <p>23 consulting?</p> <p>24 Q. Well, when did the consulting end?</p>	<p>276</p> <p>1 A. I don't know what those arrangements</p> <p>2 were.</p> <p>3 Q. You didn't ask those questions?</p> <p>4 A. No.</p> <p>5 Q. Okay. And have you received any payments</p> <p>6 from any law firms relating to anything having to do</p> <p>7 with Pharmacia or Pfizer since 2008?</p> <p>8 A. No.</p> <p>9 Q. And are you getting paid -- did you get</p> <p>10 paid or are you getting paid for your prep time for</p> <p>11 today's deposition?</p> <p>12 A. No, I'm not.</p> <p>13 Q. Okay. And why is that different than the</p> <p>14 other deposition?</p> <p>15 MR. HOFF: To the extent you have to answer</p> <p>16 that -- you can answer -- you can answer that</p> <p>17 question based upon conversations with counsel, I'll</p> <p>18 instruct you not to answer.</p> <p>19 Independent information other than</p> <p>20 conversation with counsel, you can answer to that</p> <p>21 extent.</p> <p>22 BY THE WITNESS:</p> <p>23 A. So I don't know what all this means. All</p> <p>24 I know is I'm not being paid.</p>



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<p>277</p> <p>1 BY MR. SAHAM:</p> <p>2 Q. And do you think it's because you're a</p> <p>3 defendant in this case and they don't want to pay a</p> <p>4 defendant because it would create bias?</p> <p>5 MR. HOFF: Objection.</p> <p>6 BY THE WITNESS:</p> <p>7 A. I don't know.</p> <p>8 BY MR. SAHAM:</p> <p>9 Q. And what do you do today? Like, what --</p> <p>10 are you still working or are you retired?</p> <p>11 A. I do consulting.</p> <p>12 Q. And do you do any -- none for Pfizer or</p> <p>13 Pharmacia -- well, there is no Pharmacia, but</p> <p>14 anything for Pfizer?</p> <p>15 A. No.</p> <p>16 Q. Okay. For other pharmaceutical</p> <p>17 companies?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. Anything related to Cox-II</p> <p>20 inhibitors?</p> <p>21 A. Anything related to Cox-II inhibitors?</p> <p>22 Some of the companies I deal with are dealing with</p> <p>23 compounds that -- that may be in the family of</p> <p>24 NSAIDs where the Cox-II data is pertinent. So in</p>	<p>279</p> <p>1 Q. And specifically, I only want to ask you</p> <p>2 a question about the last page of the document, but</p> <p>3 I'd ask you just generally, do you recognize this,</p> <p>4 or is it like all the other documents, you just</p> <p>5 can't say one way or the other whether you've seen</p> <p>6 it before?</p> <p>7 A. I don't recall seeing this -- having seen</p> <p>8 this before.</p> <p>9 Q. Okay. But you don't dispute one way or</p> <p>10 the other that it came out of your custodial</p> <p>11 electronic files?</p> <p>12 A. I can't -- I don't remember either way.</p> <p>13 Q. Okay. Now, I want to refer you to the</p> <p>14 last page of the document, the second bullet point.</p> <p>15 And it says, "Make clear when results are presented</p> <p>16 for data truncated at 6 months."</p> <p>17 Do you see that?</p> <p>18 A. I see that phrase, yes.</p> <p>19 Q. Okay. And that wasn't done in the JAMA</p> <p>20 article? It doesn't indicate -- well, strike --</p> <p>21 strike that. That's a bad question.</p> <p>22 Do you believe this is an accurate</p> <p>23 statement that you should make clear when results</p> <p>24 are presented for data truncated in six months?</p>
<p>278</p> <p>1 that sense, yes, but nothing related specifically to</p> <p>2 Celecoxib. None of the companies do anything with</p> <p>3 Celecoxib.</p> <p>4 Q. Okay. I want to show you some -- a</p> <p>5 document that I'm marking as Plaintiffs'</p> <p>6 Exhibit 268.</p> <p>7 (WHEREUPON, a certain document was</p> <p>8 marked Plaintiffs' Deposition</p> <p>9 Exhibit No. 268, for identification,</p> <p>10 as of 12/10/2010.)</p> <p>11 BY MR. SAHAM:</p> <p>12 Q. And like we have previously, I'll</p> <p>13 represent to you that this document was produced</p> <p>14 from your custodial files or indicates that it was</p> <p>15 produced from your custodial file.</p> <p>16 Take a look at that document.</p> <p>17 MR. SAHAM: And for the record, Plaintiffs'</p> <p>18 Exhibit 268 bears the Bates numbers DEFS 00675735</p> <p>19 through 740.</p> <p>20 And at the top, it says, Draft 6.25.00</p> <p>21 Minutes Cox-II Inhibitors Clinical Safety Committee</p> <p>22 Meeting, 7 June 2000, Doubletree Hotel, O'Hare -</p> <p>23 Rosemont, Executive Summary.</p> <p>24 BY MR. SAHAM:</p>	<p>280</p> <p>1 A. I just want to read this, the context of</p> <p>2 what they're -- who's saying it and when they're</p> <p>3 saying it.</p> <p>4 Okay. So the question is?</p> <p>5 Q. My question to you is -- and I read to</p> <p>6 you that statement in the bullet point.</p> <p>7 Do you believe that's an accurate</p> <p>8 statement?</p> <p>9 A. That it's accurate that somebody made the</p> <p>10 statement?</p> <p>11 Q. No. Do you think that's true that you</p> <p>12 should make clear when results are presented for</p> <p>13 data truncated at six months?</p> <p>14 A. I'm not sure I didn't understand the</p> <p>15 phrase, "make clear when results."</p> <p>16 Q. Do you -- do you believe that if you're</p> <p>17 talking about the 6-month data publicly, you should</p> <p>18 say, look, these results are the 6-month data, not</p> <p>19 the entire study data?</p> <p>20 A. We presented the -- the valid data. And</p> <p>21 in every public presentation, we acknowledged that</p> <p>22 this was valid data from a study no longer than six</p> <p>23 months.</p> <p>24 Q. Well, I want to turn your attention back</p>



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<p style="text-align: center;">281</p> <p>1 to Exhibit 67, the press release we had so much fun 2 with earlier, this one (indicating) probably way at 3 the bottom somewhere. 4 MR. HOFF: Which one? 5 MR. SAHAM: It's the press release that we 6 stipulated was the press release, Exhibit 67. 7 BY MR. SAHAM: 8 Q. Here it is, sir. 9 A. Thank you. 10 Q. You would agree with me that Exhibit 67 11 itself does not make clear that some of the data 12 being referred to, specifically this nonaspirin 13 data, is based on the truncated six-months' results; 14 is that correct, sir? 15 A. The data that is quoted here references 16 Dr. Silverstein, very clearly, of what 17 Dr. Silverstein presented at the American College of 18 Physicians, which was the 6-month data. 19 Q. But Exhibit 67, specifically other than 20 the reference to Silverstein presentation, doesn't 21 make clear that the sentence, "Celebrex was also 22 associated with numerically fewer ulcer 23 complications than the NSAID comparators among all 24 patients, and 64 percent fewer of these serious</p>	<p style="text-align: center;">283</p> <p>1 attachments. 2 Do you have any reason to believe you 3 didn't receive this and the attachments on or about 4 March 20, 2000? 5 My question is -- my first question is, 6 do you recognize this? 7 A. No, I don't. 8 Q. And do you have any reason to believe you 9 didn't receive the -- this document which has been 10 marked as Exhibit 27 on or about March 20th, 2000? 11 A. Well -- so I want to distinguish between 12 the e-mail which has my name on -- on it, and then 13 there are attachments which do not match the icons 14 on the e-mail cover page. 15 Q. Can I turn your attention to the second 16 to the last page of the document? And that's 17 labeled Updated: CLASS Steering Committee, correct, 18 2/21/2000? 19 A. Yes. 20 Q. And the icon on the front page of the 21 document, the third one is also labeled Steering 22 document 0 -- 000320. 23 Does that appear to be -- or I'm sorry, 24 it says 000320 CLASS Steering.doc?</p>
<p style="text-align: center;">282</p> <p>1 events among nonaspirin users -- a statistically 2 significant difference," it does not make clear, 3 within the confines of Exhibit 67, that that 4 conclusion is based on the 6-month data, does it, 5 sir? 6 A. I am saying that it does reference back 7 to Dr. Silverstein, which was the six months. 8 And I'd like to just make a comment that 9 if this is true, the other document you gave me 10 where they were commenting, the -- the data safety 11 board, my interpretation is that they were talking 12 about scientific publications. Because the data 13 safety monitoring board is a scientific group, not a 14 group that gets involved in press releases. 15 So taking the two -- trying to merge the 16 two as one thing, I don't think, is consistent. 17 Q. I want to show you what's previously been 18 marked in this litigation as Plaintiffs' Exhibit 27. 19 Could you take a look at that document. 20 And this is a cover e-mail from Carolyn 21 Wilson to George Geis and others. Subject, 22 Notes/Action Items 3/20/00 CLASS Steering Team 23 Meeting. 24 Do you see that? And then it has three</p>	<p style="text-align: center;">284</p> <p>1 A. Yes. 2 Q. So does that -- well, certainly, I don't 3 know if that's -- here, it says -- it says in the -- 4 in the e-mail there, it says, PR options provided by 5 Mr. Fleming are in 03200 CLASS PR options. 6 So these are all labeled 0000320. But 7 all I'm getting at is, that last icon says Steering 8 doc, and then the last two pages of Exhibit 27 are 9 also labeled at the top, subject, Updated: CLASS 10 Steering Committee; is that correct? 11 A. It's correct, but they don't match. 12 Q. But it would be consistent that this is 13 the steering document, or you don't know one way or 14 the other? 15 A. I -- if I had received this and somebody 16 passed it to me, I would say, are you sure that this 17 is the attachment, because it doesn't have the same 18 title. 19 Q. And you're not disputing -- you just 20 don't know one way or another whether you received 21 this document that is addressed to you as Steven 22 Geis with three attachments? 23 A. I don't recall having seen this. 24 Q. And you -- but you're not disputing that</p>



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<p>285</p> <p>1 the Bates numbers in the bottom right-hand corner of</p> <p>2 the document, which bear DEF 0 -- I'm sorry,</p> <p>3 DEFS 01574807 through 817, that those are</p> <p>4 consecutively numbered? You wouldn't dispute me on</p> <p>5 that, would you, sir?</p> <p>6 A. Yes, the -- the numbers go from 07</p> <p>7 through 17.</p> <p>8 Q. And the second to the last page of the</p> <p>9 document, 816, the one that's labeled Updated:</p> <p>10 CLASS Steering Committee, it lists the required</p> <p>11 attendees, and one of them is George S. Geis.</p> <p>12 Does that appear to be referring to</p> <p>13 yourself, sir?</p> <p>14 A. I would assume so.</p> <p>15 Q. And if you drop down to the bottom of</p> <p>16 this document, which is the Updated CLASS Steering</p> <p>17 Committee, it appears to be notes or minutes, the --</p> <p>18 I'm almost to the bottom of the document. It says,</p> <p>19 "Worse case: we have to attack the trial design if</p> <p>20 we do not see the results we want."</p> <p>21 Do you see that?</p> <p>22 A. I see that.</p> <p>23 Q. Do you recall having discussions before</p> <p>24 the data was unblinded for CLASS that if you didn't</p>	<p>287</p> <p>1 Q. And those two statements are</p> <p>2 contradictory of one other, aren't they, sir?</p> <p>3 MR. HOFF: Objection to form.</p> <p>4 BY THE WITNESS:</p> <p>5 A. They're contradictory?</p> <p>6 BY MR. SAHAM:</p> <p>7 Q. That if you don't get what you want, you</p> <p>8 got to attack the design, but if you get what you</p> <p>9 want, then you need to justify the design. Isn't</p> <p>10 that contradictory to you?</p> <p>11 Is that kosher, in your opinion, to -- to</p> <p>12 attack the design if you don't like the results and</p> <p>13 to support the design if you like the results?</p> <p>14 MR. HOFF: Objection to form.</p> <p>15 BY THE WITNESS:</p> <p>16 A. So I'm a clinician and a scientist who's</p> <p>17 been in this industry for 20 years. And it is my</p> <p>18 practice and the practice of all the scientists and</p> <p>19 clinicians I worked with that you do a study, you</p> <p>20 analyze the study as predicted, you identify the</p> <p>21 valid results and you report them, and you report</p> <p>22 the design as it was conducted.</p> <p>23 Whatever is said here, I don't know who</p> <p>24 wrote it, what they're thinking and what their</p>
<p>286</p> <p>1 get what you want, you were going to attack the</p> <p>2 trial design?</p> <p>3 A. There were no discussions of that sort</p> <p>4 that I recall. And I would like to point out,</p> <p>5 "required attendees." I don't know who wrote this,</p> <p>6 but it was not common practice to require my</p> <p>7 attendants anywhere, with the exception of through</p> <p>8 my supervisors. And none of these people would have</p> <p>9 been my supervisors.</p> <p>10 Q. And you don't --</p> <p>11 A. I don't want to give the -- I don't want</p> <p>12 to give you the impression because somebody said</p> <p>13 "required," I was there.</p> <p>14 Q. It doesn't -- you don't dispute that</p> <p>15 that's what the document says? It says, "Worse</p> <p>16 case: we have to attack the trial design if we do</p> <p>17 not see the results we want."</p> <p>18 It does say that, doesn't it?</p> <p>19 A. That is the wording of this document.</p> <p>20 Q. And then the next bullet point says,</p> <p>21 "Best case: data is all we want and we go forward;</p> <p>22 will need to justify our trial design."</p> <p>23 Do you see that?</p> <p>24 A. I see that.</p>	<p>288</p> <p>1 intent is. But it is not consistent with how I</p> <p>2 think and I have acted in my career.</p> <p>3 BY MR. SAHAM:</p> <p>4 Q. I want to show you what I'm marking as</p> <p>5 Plaintiffs' Exhibit 269.</p> <p>6 (WHEREUPON, a certain document was</p> <p>7 marked Plaintiffs' Deposition</p> <p>8 Exhibit No. 269, for identification,</p> <p>9 as of 12/10/2010.)</p> <p>10 BY MR. SAHAM:</p> <p>11 Q. Do you recognize that document?</p> <p>12 MR. SAHAM: Plaintiffs' Exhibit 269, for the</p> <p>13 record, bears Bates numbers DEFS 00416486 through</p> <p>14 88. And the first page of the document is an e-mail</p> <p>15 from Kerstin Schultz to Michael Friedman, George</p> <p>16 Geis and others.</p> <p>17 BY MR. SAHAM:</p> <p>18 Q. Do you have any reason to believe you</p> <p>19 didn't -- that this e-mail wasn't sent to you on or</p> <p>20 about March 21st of 2000?</p> <p>21 A. Here, let me take a look.</p> <p>22 So your question?</p> <p>23 Q. Do you have any reason to believe you</p> <p>24 didn't receive this e-mail in the ordinary course of</p>



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<p>289</p> <p>1 your employment on or about March 21st, 2000, at</p> <p>2 Pharmacia?</p> <p>3 A. I don't recognize it.</p> <p>4 Q. Okay. But you -- you have no reason to</p> <p>5 believe it wasn't sent to you?</p> <p>6 A. Either way, because I don't recognize it.</p> <p>7 Q. Okay. And do you know who Mike C. is?</p> <p>8 A. Mike C.?</p> <p>9 Q. Yeah, that's referred to in the third</p> <p>10 bullet point. It says, "As a contingency in case</p> <p>11 one arm in the CLASS trial doesn't separate, Mike</p> <p>12 C/RICH M to look into whether we can lump the CLASS</p> <p>13 data together and never show the separate arms."</p> <p>14 Do you see that?</p> <p>15 Do you know who Mike C. is?</p> <p>16 A. I don't know who they're referring to.</p> <p>17 I'd only be speculating.</p> <p>18 Q. Well, who do you think Mike C. is?</p> <p>19 A. I -- you know, I really don't know.</p> <p>20 Q. Okay. What about Rich M.? Would that be</p> <p>21 Richard Montwill?</p> <p>22 A. I don't know if that's who they're</p> <p>23 referring to. It's just -- it's the initials, but I</p> <p>24 don't know if that's who they're referring to.</p>	<p>291</p> <p>1 came out of your custodial electronic files, as</p> <p>2 indicated on the last page of the -- well, actually,</p> <p>3 again, this one doesn't have it, but I would</p> <p>4 indicate there is -- there was a marked report that</p> <p>5 showed that it comes from your files.</p> <p>6 BY THE WITNESS:</p> <p>7 A. Is -- are you asking me --</p> <p>8 BY MR. SAHAM:</p> <p>9 Q. No, I'm telling you --</p> <p>10 A. -- a question about it?</p> <p>11 Q. -- it was -- well, first, I'm telling you</p> <p>12 it was produced. And I'm asking --</p> <p>13 A. Okay.</p> <p>14 Q. Let me -- let me say it one thing at a</p> <p>15 time because we're -- so I don't torture the</p> <p>16 reporter.</p> <p>17 But I'm -- I'm representing to you this</p> <p>18 came out of your custodial files. It was produced</p> <p>19 by defense counsel as having come from your files.</p> <p>20 And my question to you is, do you</p> <p>21 recognize it?</p> <p>22 A. I don't recognize it.</p> <p>23 Q. Okay. Do you have any reason to believe</p> <p>24 this wasn't a document produced from you files?</p>
<p>290</p> <p>1 Q. And who's Kerstin Schultz?</p> <p>2 A. I don't -- I -- I know of a Kerstin</p> <p>3 Schultz who worked at Searle, but I don't know what</p> <p>4 her capacity was.</p> <p>5 Q. And the subject line of this e-mail is</p> <p>6 Celebrex War Meeting -- 3/21 Action Items -- and an</p> <p>7 Updated Rolling Agenda; is that correct?</p> <p>8 A. That's what this reads.</p> <p>9 Q. Okay. But you just don't recall seeing</p> <p>10 this document?</p> <p>11 A. I -- that's correct, I don't recall</p> <p>12 seeing this.</p> <p>13 Q. But you don't dispute that it was sent to</p> <p>14 you?</p> <p>15 A. I don't remember either way.</p> <p>16 Q. Okay. I want to show you what's</p> <p>17 previously been marked in this litigation as</p> <p>18 Plaintiffs' Exhibit 81.</p> <p>19 Could you please take a look at that</p> <p>20 document and tell me if you recognize it?</p> <p>21 MR. SAHAM: And it's entitled -- set of slide's</p> <p>22 entitled Celebrex long-term safety study update</p> <p>23 March 21, 2000.</p> <p>24 And, again, I would represent that this</p>	<p>292</p> <p>1 A. Well, the only thing I'll say is, some</p> <p>2 things you give me, you have a page that's -- that</p> <p>3 acknowledges it, and other times you give me</p> <p>4 documents without that page but you tell me verbally</p> <p>5 it is.</p> <p>6 So in the context that I believe what</p> <p>7 you're telling me is true --</p> <p>8 Q. You just don't have any independent</p> <p>9 recollection?</p> <p>10 A. I don't have any independent</p> <p>11 recollection --</p> <p>12 Q. Okay. I'd like to --</p> <p>13 A. -- of seeing this.</p> <p>14 Q. -- turn your attention to page 7 of this</p> <p>15 document. And it's a slide that says Contingencies</p> <p>16 Defend Celebrex Data.</p> <p>17 Do you see that?</p> <p>18 A. I do.</p> <p>19 Q. And then the first bullet point says,</p> <p>20 "Neither arm separates."</p> <p>21 Do you see that?</p> <p>22 A. I do.</p> <p>23 Q. And then under that, it says, "Must</p> <p>24 announce results by June due to stock materiality."</p>



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<p>293</p> <p>1 Do you recall anyone ever telling you</p> <p>2 that the CLASS results had to be announced by</p> <p>3 June of -- of 2000 due to stock materiality?</p> <p>4 A. No.</p> <p>5 Q. Do you have any understanding as to what</p> <p>6 that means?</p> <p>7 A. No, I don't.</p> <p>8 Q. The next bullet point says, "Explain</p> <p>9 through statistical glitches."</p> <p>10 Do you recall being any conversations or</p> <p>11 discussions regarding how to explain the CLASS</p> <p>12 results through statistical glitches?</p> <p>13 A. I never heard the phrase or the words --</p> <p>14 phrase "statistical glitches."</p> <p>15 Q. What about any discussions regarding the</p> <p>16 need to disclose the CLASS data prior to June 2000</p> <p>17 due to stock materiality, do you have any</p> <p>18 recollection of anything like that?</p> <p>19 A. None at all.</p> <p>20 Q. And you have no idea -- if I'm actually</p> <p>21 correct -- and you -- I don't know whether you</p> <p>22 believe me or not, but this document came from your</p> <p>23 files.</p> <p>24 Do you have any understanding why this</p>	<p>295</p> <p>1 of the state of Illinois?</p> <p>2 A. No.</p> <p>3 Q. And it's correct -- I know we've covered</p> <p>4 this, but it's correct that you were working on</p> <p>5 Celebrex and the CLASS trial as part of your</p> <p>6 employment at Pharmacia?</p> <p>7 A. Yes, that's true.</p> <p>8 Q. I want to show you what's previously been</p> <p>9 marked as Plaintiffs' Exhibit 79.</p> <p>10 Could you take a look at Plaintiffs'</p> <p>11 Exhibit 79, please.</p> <p>12 MR. SAHAM: And Plaintiffs' Exhibit 79 is an</p> <p>13 e-mail from George S. Geis dated March 19, 2000, to</p> <p>14 Kenneth Verburg, subject, CLASS analyses.</p> <p>15 And it states -- and then it has an</p> <p>16 attachment. But the first page of the document,</p> <p>17 it's a two-page document, an e-mail from you to Ken</p> <p>18 Verburg.</p> <p>19 BY MR. SAHAM:</p> <p>20 Q. It states, Ken, here is a list of</p> <p>21 additional analyses and slides that we might want to</p> <p>22 do. Let me know what you think. Note: I've</p> <p>23 included the date and time. I wrote this for</p> <p>24 version control.</p>
<p>294</p> <p>1 document would be in your files?</p> <p>2 A. No. It -- I think one thing to just get</p> <p>3 the context of what was going around at this time</p> <p>4 with the Pfizer codevelopment, comarketing group</p> <p>5 with Searle, there were multiple committees related</p> <p>6 to Cox-II. Then you have Pharmacia coming in around</p> <p>7 that time, and other committees were being</p> <p>8 developed.</p> <p>9 The CLASS study was of interest to a lot</p> <p>10 of people and a lot of committees, and because of my</p> <p>11 role in overseeing the team working on it, I was</p> <p>12 copied on tons of e-mails, and tons of attachments</p> <p>13 were sent to me. So I just want to make sure, for</p> <p>14 the record, that context is described.</p> <p>15 Q. And is it fair to say that those tons of</p> <p>16 e-mails and tons of reports, et cetera, regarding</p> <p>17 CLASS that were sent to you, they were sent to you</p> <p>18 in your business capacity as an employee of</p> <p>19 Pharmacia; is that correct, sir?</p> <p>20 A. Anything that I would have received</p> <p>21 related to CLASS would have been as an employee of</p> <p>22 Searle and then Pharmacia.</p> <p>23 Q. So they weren't personal -- they weren't</p> <p>24 sent to you personally in your capacity as a citizen</p>	<p>296</p> <p>1 And then it has an attached -- an icon</p> <p>2 indicating there's an attached document, and then</p> <p>3 there's an attached page to it.</p> <p>4 Do you recognize this document?</p> <p>5 A. Let me take a look.</p> <p>6 I have a vague recollection of this, yes.</p> <p>7 Q. And is this a document you would have</p> <p>8 drafted in the ordinary scope of your employment at</p> <p>9 Pharmacia?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. And if you look at the second page</p> <p>12 of the document, the analyses 1 through 4 that you</p> <p>13 describe, C-S-U-G-Is without ASA over 12 months with</p> <p>14 stats.</p> <p>15 No. 2, C-S-U-G-Is, without ASA over</p> <p>16 six months with stats.</p> <p>17 No. 3, PUBs with and without ASA over</p> <p>18 12 months with stats.</p> <p>19 And No. 4, PUBs with and without ASA over</p> <p>20 six months with stats.</p> <p>21 If you look at those four, do they match</p> <p>22 up pretty closely, if not identically, with Tables 1</p> <p>23 through 4 in Exhibit 66, the final report, the</p> <p>24 synopsis on pages 6 and 7 of the Exhibit 66, the</p>



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<p>297</p> <p>1 final report that we looked at earlier? It's the</p> <p>2 big fat document in the pile there.</p> <p>3 A. So just like you, I want to be precise.</p> <p>4 So number one, clinically significant</p> <p>5 upper GI events without aspirin over 12 months, now,</p> <p>6 our terminology at this time was to sort of,</p> <p>7 shorthand, call the entire study analysis 12 months,</p> <p>8 okay, to make -- make -- make that clear.</p> <p>9 With statistics, that does match with the</p> <p>10 second portion -- excuse me -- the second portion,</p> <p>11 the bottom portion of Table 2 in the report. And</p> <p>12 it -- and it matches in the sense that we're doing</p> <p>13 the analysis over six months without aspirin.</p> <p>14 No. 2 on the list does match Table 1, the</p> <p>15 second half of it without aspirin with statistics.</p> <p>16 No. 3 matches Table 4, PUBs with and</p> <p>17 without aspirin over 12 months. Again, aspirin as</p> <p>18 shorthand for the entire study period with stats</p> <p>19 matches Table 4.</p> <p>20 And then No. 4 on the list, PUBs with and</p> <p>21 without aspirin over six months with stats is --</p> <p>22 matches Table 3.</p> <p>23 Q. And the next number there says,</p> <p>24 Kaplan-Meier of withdrawals for any cause.</p>	<p>299</p> <p>1 the data.</p> <p>2 And in the -- in -- in that context,</p> <p>3 trying to understand, were we getting withdrawals in</p> <p>4 patients who were at risk for developing an ulcer</p> <p>5 complication. And that was how the initial thinking</p> <p>6 was beginning of, is there bias developing in this</p> <p>7 study over time?</p> <p>8 So this was in the early stages of</p> <p>9 understanding the data, asking for analyses that</p> <p>10 could help us understand it, which ultimately led</p> <p>11 to, yeah, you were getting not only withdrawals of</p> <p>12 patients with risk factors, but differential</p> <p>13 withdrawals in the treatment groups, which rendered</p> <p>14 the data beyond six months invalid.</p> <p>15 Q. And you're -- you're talking about this</p> <p>16 two days after the data was unblinded?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And the next bullet point under 6</p> <p>19 says risk factors for C-S-U-G-Is?</p> <p>20 A. Yes. And that's what I was just talking</p> <p>21 about as I was describing -- what I was -- when I</p> <p>22 was looking at early withdrawals.</p> <p>23 Q. Okay. And then dropping down to the</p> <p>24 bottom of the CLASS plan that you drafted on</p>
<p>298</p> <p>1 What are you communicating there to</p> <p>2 Dr. Verburg?</p> <p>3 A. A Kaplan-Meier plot is a curve that says,</p> <p>4 on the abscissa, is time; on the ordinate, is some</p> <p>5 type of outcome that you're interested. And I'm</p> <p>6 saying, on the ordinate, look at withdrawals.</p> <p>7 So you have time on the abscissa,</p> <p>8 withdrawals on the ordinate. And what they do is</p> <p>9 they plot over time how many -- what -- how many</p> <p>10 people or what percent of people have withdrawn over</p> <p>11 time. And it creates a curve called a Kaplan-Meier</p> <p>12 curve.</p> <p>13 And so what I -- what I -- if I can get</p> <p>14 back into what I was thinking at the time was the</p> <p>15 idea to say, were most of the -- where were the</p> <p>16 withdrawals occurring over time in the study? That</p> <p>17 was the intent.</p> <p>18 Q. And No. 6, that's for early -- to do that</p> <p>19 for early withdrawals?</p> <p>20 A. So No. 6 was so -- again, this is dated</p> <p>21 March 19th, 2000. We received the -- the -- the --</p> <p>22 the -- the first set of analyses from CLASS a couple</p> <p>23 days before, and this was in the context, as I was</p> <p>24 describing earlier, of people trying to understand</p>	<p>300</p> <p>1 March 19, 2000, it says Story.</p> <p>2 Do you see that? And then there's</p> <p>3 three -- three points?</p> <p>4 A. I do see this.</p> <p>5 Q. In the first point you write, Over first</p> <p>6 six months, numerically, results are as expected:</p> <p>7 You wrote that on March 19th, 2000 --</p> <p>8 A. If -- if this is -- if this is exactly</p> <p>9 what I put together. And, yes, this does look</p> <p>10 right, but I don't remember exactly this. But, yes,</p> <p>11 that's what this says.</p> <p>12 Q. Okay. And then the second point says,</p> <p>13 "However, high ASA use in early drops in the Diclo</p> <p>14 group confounded the results."</p> <p>15 You wrote that on or about March 19,</p> <p>16 2000?</p> <p>17 A. It appears that in this document, that's</p> <p>18 what this says.</p> <p>19 Q. Okay. And this was a document that was</p> <p>20 created in the ordinary scope of business at</p> <p>21 Pharmacia?</p> <p>22 A. Assuming that this is the accurate</p> <p>23 document, yes.</p> <p>24 Q. Okay. And then the bullet point says,</p>



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<p>301</p> <p>1 Slide of C-S-U-G-Is over six months without ASA use</p> <p>2 (possibly two panel left side with ASA data, right</p> <p>3 side without ASA)?</p> <p>4 A. Yes.</p> <p>5 Q. And then the next bullet point says,</p> <p>6 Slide of early withdrawals due to GI symptoms (shows</p> <p>7 much earlier drops in Diclo)?</p> <p>8 A. Yes.</p> <p>9 Q. And then No. 3, it says, Over second six</p> <p>10 months, patients in NSAID groups who are at risk of</p> <p>11 CSUGI have pulled out, therefore all Kaprin --</p> <p>12 Kaplan-Meier lines merge.</p> <p>13 Do you see that?</p> <p>14 A. I do.</p> <p>15 Q. And is that when we were looking at --</p> <p>16 earlier, we looked at sort of a big PowerPoint slide</p> <p>17 where the lines were coming together -- or the</p> <p>18 Celebrex versus the NSAIDs were becoming closer at</p> <p>19 12 months as compared to 6 months.</p> <p>20 Is that a -- a simplistic rend- --</p> <p>21 rend- -- rendering of a Kaplan- -- Kaplan-Meier</p> <p>22 line?</p> <p>23 A. That --</p> <p>24 MR. HOFF: Objection to form.</p>	<p>303</p> <p>1 of -- of -- of, like, the -- the percentage of</p> <p>2 complications that has occurred.</p> <p>3 Q. But Kaplan-Meier rates -- or lines track</p> <p>4 event rates over time? I mean, is that an overly</p> <p>5 simplistic way to say it?</p> <p>6 A. It's overly simplistic, but I don't think</p> <p>7 it's grossly inaccurate.</p> <p>8 Q. And -- and then this slide is doing the</p> <p>9 same thing, it's -- it's tracking crude event rates</p> <p>10 over time?</p> <p>11 A. Yes, it is.</p> <p>12 Q. And it's showing that there's less of a</p> <p>13 difference over time at the 12 months for the NSAIDs</p> <p>14 as compared to Celebrex as there was at 6 months?</p> <p>15 A. Yes, in this portion that we consider the</p> <p>16 invalid portion of the study.</p> <p>17 MR. SAHAM: We got to change the tape.</p> <p>18 Hopefully the last time we have to change the tape,</p> <p>19 but we need to take a break.</p> <p>20 THE VIDEOGRAPHER: Going off the video record</p> <p>21 at 4:26 p.m.</p> <p>22 This is the end of Tape No. 5.</p> <p>23 (WHEREUPON, a short recess was</p> <p>24 had.)</p>
<p>302</p> <p>1 BY THE WITNESS:</p> <p>2 A. The -- I'd have to look exactly at the</p> <p>3 graph. But this was as you -- in the couple days</p> <p>4 after we received the data and we were trying to</p> <p>5 understand the data, this was early attempts to go</p> <p>6 through the rationale as to what was and was not the</p> <p>7 valid set of data. And that's what we were -- what</p> <p>8 I was attempting to do here.</p> <p>9 It wasn't the final rendition of our</p> <p>10 understanding of the data, but an early one, in</p> <p>11 asking for analyses to help understand the data.</p> <p>12 BY MR. SAHAM:</p> <p>13 Q. If I could ask you to grab 250, the</p> <p>14 bottom line, and look again at slide 43,</p> <p>15 Complication Rates (All) Over 12 Months.</p> <p>16 Are those lines Kaplan-Meier lines?</p> <p>17 A. These precisely are not Kaplan-Meier</p> <p>18 lines, because Kaplan-Meier lines do not record</p> <p>19 crude rates like this.</p> <p>20 Q. What do Kaplan-Meier lines do that's</p> <p>21 different than this slide?</p> <p>22 A. The ordinate -- I'd have to pull one out</p> <p>23 of the report, but it's in the appendix. The</p> <p>24 ordinate is not crude rates. It is another measure</p>	<p>304</p> <p>1 THE VIDEOGRAPHER: Going back on the video</p> <p>2 record at 4:40 p.m.</p> <p>3 This is the beginning of Tape No. 6.</p> <p>4 BY MR. SAHAM:</p> <p>5 Q. Showing you what's been previously marked</p> <p>6 in this litigation as Plaintiffs' Exhibit 80. It's</p> <p>7 a two-page document. The first page is an e-mail</p> <p>8 bearing Bates number DEFS 00886542. The second page</p> <p>9 bears Bates number same, but last two are 43. And</p> <p>10 it's an attachment labeled CLASS, March 20, 2000,</p> <p>11 CLASS Analyses - Other considerations.</p> <p>12 The e-mail is from George Geis -- George</p> <p>13 S. Geis, March 21, 2000, to James Lefkowitz. And it</p> <p>14 cc's various other individuals on your team.</p> <p>15 And I'd ask you if you recognize this</p> <p>16 document which has been marked as Plaintiffs'</p> <p>17 Exhibit 80?</p> <p>18 A. So the question is?</p> <p>19 Q. Do you recognize it?</p> <p>20 A. I do vaguely recognize it.</p> <p>21 Q. And is this a document that you drafted</p> <p>22 at your employment at Pharmacia on or about</p> <p>23 March 21st, 2000?</p> <p>24 A. Yes.</p>



<p style="text-align: center;">305</p> <p>1 Q. And you did so in the ordinary course of</p> <p>2 your employment there?</p> <p>3 A. It's -- it's -- yes, I did.</p> <p>4 Q. Okay. And you wrote to Dr. Lefkowitz and</p> <p>5 your other team members, "As you heard last evening,</p> <p>6 Mike and I reviewed the available data and he</p> <p>7 believes we have a good story; although, not one as</p> <p>8 simple as we had hoped."</p> <p>9 Is that Mike referring to Mike Friedman,</p> <p>10 your boss?</p> <p>11 A. It is.</p> <p>12 Q. And when you say, have a good story, but</p> <p>13 not as simple -- simple one as you -- you would have</p> <p>14 hoped, what -- what did you mean in writing that?</p> <p>15 A. So last evening would have been Monday,</p> <p>16 March 20th, 2000, which would have been, I guess,</p> <p>17 two or three days after we had received the first</p> <p>18 set of data from the CLASS trial.</p> <p>19 And as I discussed earlier, which was our</p> <p>20 common practice, people sort of sat down, went off</p> <p>21 site and focused on how to understand the data,</p> <p>22 how -- and how -- what other analyses might be</p> <p>23 helpful in understanding the data as it was</p> <p>24 originally presented.</p>	<p style="text-align: center;">307</p> <p>1 Celebrex, the understanding of the design of the</p> <p>2 trial, the interactions with the FDA, he was new to</p> <p>3 it all.</p> <p>4 So his -- he did not have the history to</p> <p>5 understand our presentation like some other people</p> <p>6 who were involved historically would be. So he had</p> <p>7 some questions. He had some recommendations. He</p> <p>8 asked for us to consider other analyses.</p> <p>9 And this e-mail was to honor his</p> <p>10 questions, honor his request for analyses for the</p> <p>11 team to consider to get a -- the best understanding</p> <p>12 possible of the CLASS data.</p> <p>13 Q. When did Dr. Silverstein and Dr. Simon</p> <p>14 and the other external authors receive the data?</p> <p>15 A. So in terms of receive the data, no one,</p> <p>16 as I recall, received it. What we did is -- and I</p> <p>17 believe the date was around March 31st -- we had a</p> <p>18 meeting with the -- if you will, the external</p> <p>19 authors at a hotel where we presented the data and</p> <p>20 presented all the various analyses that we had and</p> <p>21 our interpretation and understanding of the data.</p> <p>22 So in the sense, did they receive it? No</p> <p>23 one got hard copies of anything. No one</p> <p>24 electronically was sent anything. So that was</p>
<p style="text-align: center;">306</p> <p>1 The team, during that 48 hours, was</p> <p>2 coming to an appreciation of understanding the</p> <p>3 confounders of the study and understanding why the</p> <p>4 first six months was the valid set and data beyond</p> <p>5 that were complications and symptomatic ulcers was</p> <p>6 not valid.</p> <p>7 I presented it to Mike Friedman on the</p> <p>8 evening of Monday, March 20th. So it was the first</p> <p>9 time one of us had a chance to, in our terms, and</p> <p>10 the language we used was, to tell the story, which</p> <p>11 is, here's -- was the study objectives, here was the</p> <p>12 design, here's the results, here's how we understand</p> <p>13 the data, here's our thoughts on what is the valid</p> <p>14 set, which wasn't uncommon.</p> <p>15 The first time you present it, you think</p> <p>16 it's pretty simple and clear, and your first</p> <p>17 audience says it's not as simple. It's not that</p> <p>18 simple. It's not that clear.</p> <p>19 So that's not unexpected in the context</p> <p>20 of presenting the first set of data to -- to</p> <p>21 someone.</p> <p>22 Also, I'd like to point out, Mike</p> <p>23 Friedman was new to Searle in a matter of months,</p> <p>24 and his appreciation of all of our understanding of</p>	<p style="text-align: center;">308</p> <p>1 around March 31st.</p> <p>2 As I recall, all the external authors</p> <p>3 were there with the exception of Fred Silverstein.</p> <p>4 And Fred Silverstein, I went through things by phone</p> <p>5 with him around the same time period.</p> <p>6 Q. Okay. When you say no one received it,</p> <p>7 none of the external authors received the data, but</p> <p>8 you and the folks at Pharmacia internally, you've</p> <p>9 had the data, correct?</p> <p>10 A. Yes, that's correct.</p> <p>11 Q. And then you summarized it and</p> <p>12 presented -- presented it to the external authors?</p> <p>13 A. And there were -- so -- so we summarized,</p> <p>14 but we also presented on overheads, some of the raw</p> <p>15 data that would have been in appendices of --</p> <p>16 ultimately be in the appendices of the report.</p> <p>17 So we had available to them whatever they</p> <p>18 wanted to see after we presented it. If they wanted</p> <p>19 to drill down and see more, we were available to do</p> <p>20 that.</p> <p>21 So the idea, which is consistent with our</p> <p>22 practices, were, we put our best thinking together</p> <p>23 internally, then we bring it forward to external</p> <p>24 people who are experts and say, here's what we</p>



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<p>309</p> <p>1 think. What do you think? Do you need more</p> <p>2 information? And if you do, let's try to get it to</p> <p>3 you.</p> <p>4 Q. And one of the things you brought forward</p> <p>5 to them on March 31st is that you thought the -- the</p> <p>6 data may be biased after six months due to the</p> <p>7 informative censoring, if you will?</p> <p>8 A. We -- we brought forward data in the</p> <p>9 concept that there was differential withdrawal in</p> <p>10 the treatment groups due to patients most likely to</p> <p>11 get an ulcer complication. We brought that forward</p> <p>12 and showed it to them and showed that we think it --</p> <p>13 its maximum effect was after the first six months.</p> <p>14 We brought that forward.</p> <p>15 The concept of informative censoring, in</p> <p>16 the phrase, I don't believe, was being used then.</p> <p>17 Informative censoring was not a term that I was</p> <p>18 familiar with until after the CLASS data began to be</p> <p>19 reviewed in a lot more detail.</p> <p>20 So informative censoring, I -- was not</p> <p>21 out there. But the concept of differential</p> <p>22 withdrawal of susceptible patients was presented to</p> <p>23 the external folks.</p> <p>24 Q. So the concept of bias and differential</p>	<p>311</p> <p>1 A. Yeah. We wanted to go back and -- I</p> <p>2 don't think we said create a slide. It was base --</p> <p>3 it is basically what we're calling analyses and</p> <p>4 other considerations.</p> <p>5 No. 1 isn't -- it was more about, go back</p> <p>6 to the protocol and statistical analysis plan and</p> <p>7 make -- make it clear what was defined as primary,</p> <p>8 secondary, exploratory, if those terms were used.</p> <p>9 Q. And we know from looking at the protocol</p> <p>10 that was Exhibit 77, that the primary -- the</p> <p>11 coprimary endpoints were the complicated ulcers?</p> <p>12 A. That's correct.</p> <p>13 Q. And -- and there was no description that</p> <p>14 those complicated ulcers would be looked at at any</p> <p>15 point short of the entire study in the protocol?</p> <p>16 That's a bad question.</p> <p>17 The protocol didn't say, we're going to</p> <p>18 look at these complicated ulcers at six months and</p> <p>19 for the entire study because it was a</p> <p>20 time-to-completion study?</p> <p>21 MR. HOFF: Objection to form.</p> <p>22 BY MR. SAHAM:</p> <p>23 Q. Or an event-to-completion or however you</p> <p>24 described it.</p>
<p>310</p> <p>1 withdrawal, that was presented by internal Pharmacia</p> <p>2 folks, including yourself, to the external authors</p> <p>3 on or about March 31st, 2000?</p> <p>4 A. That's correct.</p> <p>5 Q. And -- and -- and then it was also around</p> <p>6 that same time you communicated that concept to</p> <p>7 Dr. Silverstein over the phone?</p> <p>8 A. Around that time, yes. I don't remember</p> <p>9 exactly the date.</p> <p>10 Q. Okay. And looking back to the CLASS --</p> <p>11 the -- to this document that's been marked as</p> <p>12 Exhibit 80 that you drafted, the second page where</p> <p>13 it says, "CLASS Analyses - Other considerations,"</p> <p>14 No. 1 says, "As per the protocol, what were the</p> <p>15 defined primary, secondary, exploratory, et cetera,</p> <p>16 analyses?"</p> <p>17 Do you see that?</p> <p>18 A. I do.</p> <p>19 Q. And was that a question Dr. Friedman had</p> <p>20 for you, like, what's the secondary, primary and</p> <p>21 exploratory analyses?</p> <p>22 A. Yes, it was.</p> <p>23 Q. And you wanted to create a slide that</p> <p>24 answered that for him?</p>	<p>312</p> <p>1 That's a bad question.</p> <p>2 My -- my question to you is --</p> <p>3 MR. WEISS: That's two in a row.</p> <p>4 MR. SAHAM: There's, like, six bad questions</p> <p>5 pending, so I'll ask a seventh.</p> <p>6 MR. HOFF: You've got -- you've got one -- it's</p> <p>7 three strikes, you're out, I believe, in California,</p> <p>8 right?</p> <p>9 BY MR. SAHAM:</p> <p>10 Q. But -- but Dr. Geis, it's -- it's</p> <p>11 after -- the protocol doesn't lay out that you're</p> <p>12 going to look at some subset of the data at six</p> <p>13 months for those primary endpoints; is that correct,</p> <p>14 sir?</p> <p>15 A. Well --</p> <p>16 MR. HOFF: I just want you to read it back</p> <p>17 because I want to make sure I understand what the</p> <p>18 question is.</p> <p>19 MR. SAHAM: But -- but the new question.</p> <p>20 MR. HOFF: The current one.</p> <p>21 (WHEREUPON, the record was read by</p> <p>22 the reporter.)</p> <p>23 MR. HOFF: Objection to form.</p> <p>24 BY THE WITNESS:</p>



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<p style="text-align: center;">313</p> <p>1 A. The protocol outlines that this is 2 going -- this is a time-to-event study and that 3 crude rates would be analyzed and Kaplan-Meier plots 4 would be run. 5 When they run the Kaplan-Meier plots, 6 they also run tables cutting the data at 7 three months, six months. And I think there's a few 8 others, and you'll find those tables in the report. 9 BY MR. SAHAM: 10 Q. But the protocol that we were looking at 11 earlier didn't state that it was going to be looked 12 at in six months -- 13 MR. HOFF: Objection to form. 14 BY MR. SAHAM: 15 Q. -- is that correct, sir? 16 A. So the precise wording of six months in 17 the analysis plan, I do not believe is there. But 18 the Kaplan-Meier of time-to-event, as I understand 19 from the statisticians, allows for cuts anywhere 20 between the first event and the last event of the 21 study. 22 Q. And is that something you learned in your 23 preparation to testify about the topic about 24 informative censoring? You spoke to statisticians</p>	<p style="text-align: center;">315</p> <p>1 A. Yes. 2 Q. And -- and why'd you write that? 3 A. Well, in the con- -- again, although I 4 remember writing this e-mail, I don't expressly 5 remember exactly each one of these, but this was a 6 list that Mike Friedman had asked for. And in the 7 spirit of it -- of honoring his request for 8 additional analyses, we gave -- we were going to do 9 this cut. 10 But as you see, earlier, I said you may 11 have done this already. 12 So as the team was working and we -- and 13 we had, before we spoke with Friedman, come to the 14 understanding that there was bias which invalidated 15 the data after six months. It's highly -- highly 16 likely that we had the stats for six months before I 17 wrote this. 18 Q. And in No. 11, you write, "Outcomes of 19 POBs and Ulcers"? 20 A. Yes. 21 Q. Okay. I want to turn your attention to 22 what I'm marking as Plaintiffs' Exhibit 270. 23 24</p>
<p style="text-align: center;">314</p> <p>1 and they told you that the Kaplan-Meier 2 time-to-event thing would roll out for six months? 3 A. No. This -- this goes back to when 4 this -- when we were first dealing with the data and 5 trying to understand the data, we consulted 6 extensively with the statisticians of, what is it -- 7 what are appropriate analyses, and is it appropriate 8 that we can identify and use the 6-month data as the 9 valid data? And they unanimously agreed that that 10 was consistent with the whole analysis of 11 time-to-event. 12 Q. But the protocol doesn't lay out that 13 you're going to do an analysis at six months, 14 correct? 15 MR. HOFF: Objection to form. 16 BY THE WITNESS: 17 A. The precise wording stating six months, I 18 do not believe, is in the protocol, but the 19 time-to-event analysis is, which they tell me allows 20 for earlier cuts is there. 21 BY MR. SAHAM: 22 Q. Okay. Looking back at Exhibit No. 80, 23 you write number -- No. 8 on the second page, you 24 write, "Stats for 6 months (POBs and PUBs) only"?</p>	<p style="text-align: center;">316</p> <p>1 (WHEREUPON, a certain document was 2 marked Plaintiffs' Deposition 3 Exhibit No. 270, for identification, 4 as of 12/10/2010.) 5 BY MR. SAHAM: 6 Q. Could you please take a look at 7 Plaintiffs' Exhibit 270. 8 MR. SAHAM: And for the record, Plaintiffs' 9 Exhibit 270 is a one-page document bearing Bates 10 number DEFS 00113940. And, again, this one actually 11 has the attachment saying it came from your 12 custodial files. 13 BY MR. SAHAM: 14 Q. And I'd ask you if you recognize this 15 document which says, Draft 11.23.99, JAMA editorial, 16 Message Points? 17 A. I don't -- I don't recall seeing this. 18 Q. But you don't dispute this came from your 19 custodial files? 20 A. I don't -- 21 Q. Okay. In looking -- 22 A. -- either way. 23 Q. Sorry. 24 The bullet point -- I'm looking at the</p>



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<p>317</p> <p>1 sixth bullet point under JAMA editorial Message</p> <p>2 Points. It says, "You can't predict who will and</p> <p>3 won't have a bleed - and especially not with</p> <p>4 chronic, lifetime use. Only 20 percent of people</p> <p>5 with NSAID-induced bleeds ever have symptoms."</p> <p>6 Do you agree with that statement?</p> <p>7 A. So -- so first of all, I just want to</p> <p>8 make sure, I don't know who wrote this. And, again,</p> <p>9 there were a lot of people writing things and</p> <p>10 copying me on them, and some were scientists and</p> <p>11 physicians and some were people within the</p> <p>12 organization.</p> <p>13 So I don't know that that's true. I'd</p> <p>14 have to look at the data to refresh my memory about</p> <p>15 20 percent --</p> <p>16 Q. You just don't know whether it's accurate</p> <p>17 or not?</p> <p>18 A. No, I don't.</p> <p>19 Q. Okay. I want to show you what I'm</p> <p>20 marking as Plaintiffs' Exhibit 271.</p> <p>21 (WHEREUPON, a certain document was</p> <p>22 marked Plaintiffs' Deposition</p> <p>23 Exhibit No. 271, for identification,</p> <p>24 as of 12/10/2010.)</p>	<p>319</p> <p>1 A. I believe you do.</p> <p>2 Q. Okay. And you didn't do that?</p> <p>3 A. I did not.</p> <p>4 Q. I want to show you what I'm marking as</p> <p>5 Plaintiffs' Exhibit 271.</p> <p>6 Could you please take a look at</p> <p>7 Plaintiffs' Exhibit 271. And this bears the</p> <p>8 Bates numbers DEFS 00536944 through 955.</p> <p>9 And it's a two-page e-mail that has an</p> <p>10 attachment and then -- and the document's from</p> <p>11 Thomas Krol to numerous people, including Lefkowitz,</p> <p>12 Verburg, Wahba, W-a-h-b-a, and you're cc'd.</p> <p>13 Do you know who this Thomas Krol fellow</p> <p>14 is?</p> <p>15 A. I don't recall the name at all.</p> <p>16 Q. Okay. And do you have any reason to</p> <p>17 believe you didn't receive this e-mail on or about</p> <p>18 May 26, 2000?</p> <p>19 A. I don't remember either way.</p> <p>20 Q. Okay. And I'd like to refer your</p> <p>21 attention to the last three Bates numbers 950, sort</p> <p>22 of in the middle of the document. And there's a</p> <p>23 table, and under it, it says, "GI symptoms are</p> <p>24 nonetheless poor predictors of serious toxicity."</p>
<p>318</p> <p>1 BY MR. SAHAM:</p> <p>2 Q. And, again, you're not a -- a</p> <p>3 gastroenterologist, correct?</p> <p>4 A. I was -- I was not trained in</p> <p>5 gastroenterology; however, I was trained in surgery</p> <p>6 and so dealt with people with ulcers that perforated</p> <p>7 and bleeding.</p> <p>8 Q. Right. And I understand you're a medical</p> <p>9 doctor.</p> <p>10 A. I am.</p> <p>11 Q. And you did a residency? Did you</p> <p>12 complete a residency?</p> <p>13 A. I did not.</p> <p>14 Q. You did part of a residency?</p> <p>15 A. I did.</p> <p>16 Q. And then you went into work for</p> <p>17 Pharmacia?</p> <p>18 A. Correct. I also have a Ph.D. in</p> <p>19 physiology.</p> <p>20 Q. Right. And -- and -- and my question is,</p> <p>21 a gastroenterologist, that's like a specialization,</p> <p>22 correct?</p> <p>23 A. That's correct.</p> <p>24 Q. You had to do a fellowship to get it?</p>	<p>320</p> <p>1 Do you see that?</p> <p>2 A. No. Let me read this.</p> <p>3 MR. HOFF: What page are you on?</p> <p>4 MR. SAHAM: It's 950. There's a table in there</p> <p>5 and then there's some text.</p> <p>6 BY THE WITNESS:</p> <p>7 A. I see what's written here, yes.</p> <p>8 BY MR. SAHAM:</p> <p>9 Q. Okay. So I'm just reading you the</p> <p>10 sentence, "GI symptoms are nonetheless poor</p> <p>11 predictors of serious toxicity."</p> <p>12 Do you believe that's an accurate</p> <p>13 statement?</p> <p>14 A. No, I do not. I -- I just want to point</p> <p>15 out, I don't know what this is and -- and what these</p> <p>16 guys were writing, but it looks like who -- whoever</p> <p>17 Tom Krol is, is -- is taking some data and making</p> <p>18 conclusions, and I have no -- no recollection of</p> <p>19 what he's doing or why he's doing it. But --</p> <p>20 Q. Do you know --</p> <p>21 A. -- this isn't something that came -- that</p> <p>22 looks to me like it came out of the medical or the</p> <p>23 science groups at Searle.</p> <p>24 Q. Do you know who Jan Markind is?</p>



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<p>321</p> <p>1 A. Jan Markind, as I recall, was a Searle 2 employee, and she was a medical writer for what we 3 call medical affairs, which was connected to the 4 commercial side of the organization. 5 Q. I want to show you what I'm marking as 6 Plaintiffs' Exhibit 272. 7 (WHEREUPON, a certain document was 8 marked Plaintiffs' Deposition 9 Exhibit No. 272, for identification, 10 as of 12/10/2010.) 11 THE WITNESS: Can I -- can I go back and 12 just make a -- I just want to clarify a comment 13 about, symptoms are predictors -- are poor 14 predictors. I just want to be careful with the word 15 "predict." And in my answer is that there is a 16 correlation between symptoms and -- and -- and 17 clinically significant events. 18 That's what I mean when I disagree with 19 it. There is a correlation, but it is not a 20 one-to-one association or -- of symptoms versus 21 complications. I just wanted to clarify that. 22 BY MR. SAHAM: 23 Q. Thank you, sir. 24 I want to show you Plaintiffs'</p>	<p>323</p> <p>1 Q. Okay. And specifically, I want to refer 2 you to the bottom of -- in the bottom right-hand 3 corner, it says page 5, and it's a Bloomberg 4 April 17th, 2000 article by Michelle Fay Cortez 5 entitled Pharmacia's, Pfizer -- Pharmacia's, Pfizer 6 Celebrex Drug Found to Be Safer. 7 Do you see that? 8 A. I see that. 9 Q. And then you turn over to the next page, 10 which is the -- most of the body of this April 17th, 11 2000 article, and you go to the third full paragraph 12 on page 6. It says, "We really believe the data 13 are sufficiently compelling to warrant discussions 14 with the FDA," said Dr. Steve Geis, vice president 15 of the arthritis clinical program at Pharmacia's 16 Searle unit. He wouldn't predict if the results 17 were strong enough to get the warning label 18 revised." 19 Does this refresh your recollection that 20 you spoke to the press on or about April 17th, 2000, 21 regarding the CLASS trial? 22 A. No, it doesn't. 23 Q. Do you have any reason to believe that 24 this Bloomberg article is not an article that was</p>
<p>322</p> <p>1 Exhibit 272. 2 MR. SAHAM: And for the record, Plaintiffs' 272 3 bears Bates numbers DEFS 00362813 through 825. And 4 the front page of the document is an e-mail, at 5 least the top e-mail, from George S. Geis, dated 6 April 18th, 2000, to Kenneth Verburg, Richard 7 Hubbard and David Recker. And the subject is CLASS 8 Study Media Coverage 4/17. 9 And below that, there's an e-mail from 10 Diana Smith dated April 17, 2000, subject, CLASS 11 Study Media Coverage, that went to you that then you 12 forwarded to those gentlemen. 13 BY MR. SAHAM: 14 Q. And I'd ask you, first off, if you 15 recognize either -- or if you recognize this 16 document which consists of the e-mail and the 17 synopsis of CLASS Study Media Coverage, April 17th, 18 2000? 19 A. I don't recall this e-mail, neither the 20 e-mail nor the attachment. 21 Q. But you don't have any reason to believe 22 you didn't receive this in the ordinary scope of 23 your employment at Pharmacia? 24 A. I don't recall it either way.</p>	<p>324</p> <p>1 published by Michelle Fay Cortez on or about 2 April 17th, 2000? 3 A. In the sense that this is truly her 4 article, I have no reason to believe it's not 5 accurate. 6 Q. Okay. So you wouldn't -- you wouldn't 7 testify today that you didn't speak to the press on 8 April 17th -- 9 A. Correct, I don't remember. 10 Q. Okay. I want to show you what I'm 11 marking as Plaintiffs' Exhibit 273. 12 (WHEREUPON, a certain document was 13 marked Plaintiffs' Deposition 14 Exhibit No. 273, for identification, 15 as of 12/10/2010.) 16 BY MR. SAHAM: 17 Q. And, again, this is one of those 18 documents where, unfortunately, I didn't bring the 19 little page on the end, but I would represent to you 20 that this came from your custodial files. You can 21 take that representation for whatever it's worth. 22 And this document, Exhibit 273, bears 23 Bates numbers DEFS 01015928 through 5935, and it's 24 labeled 4/16, 2000, Draft, Q&amp;A Document/CLASS Trial</p>



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<p>325</p> <p>1 Results, For Internal Use Only, Not for External 2 Distribution. 3 I'd ask you if you recognize this 4 document? 5 A. I don't recall this document. 6 Q. Okay. Do you recall seeing similar 7 documents like this during your time at Pharmacia? 8 A. I have -- I've seen documents that look 9 like this where they have Q and As, but not 10 routinely. 11 Q. I want to show you what I'm marking as 12 Plaintiffs' Exhibit 274. 13 (WHEREUPON, a certain document was 14 marked Plaintiffs' Deposition 15 Exhibit No. 274, for identification, 16 as of 12/10/2010.) 17 MR. SAHAM: Ask you to take a look at 18 Plaintiffs' Exhibit 274, which for the record, bears 19 Bates numbers DEFS 00536852 through 6856. 20 BY MR. SAHAM: 21 Q. I'd ask you if you recognize this 22 document? 23 A. Could you repeat your question? 24 Q. I asked you if you recognize this</p>	<p>327</p> <p>1 A. I do. 2 Q. The -- the second paragraph there says, 3 "According to FDA, should Celebrex have exhibited 4 superiority over D (which it did not), then it would 5 have been valid to look into the contribution of 6 informative censoring. However, in the current 7 situation where a negative result was observed, IC 8 could only have been attributed if it was well 9 accepted in the particular field." 10 To your recollection, does that 11 accurately reflect Dr. Goldkind and Dr. Hong Lu, the 12 FDA medical reviewer and statistical reviewer's 13 opinion regarding the, quote-unquote, informative 14 censoring explanation? 15 A. Let me read this again. 16 I don't understand what this really says, 17 and I don't remember what Dr. Goldkind and Dr. Lu 18 presented at the advisory meeting. In a way, this 19 doesn't even make sense to me, but... 20 Q. Do you remember Winifred Begley? 21 A. I do. 22 Q. And was she, like, a regulatory affairs 23 person? 24 A. She was a -- a regulatory affairs person</p>
<p>326</p> <p>1 document? 2 A. I do not. 3 Q. Okay. But you're listed as having 4 attended a January 26 meeting with the FDA in 5 preparation for the advisory committee meeting? 6 A. Yes. 7 Q. And is that the meeting you referred to 8 earlier with Dr. Goldkind and perhaps Dr. Hong Lu? 9 A. I believe so, yes. 10 Q. Okay. And this appears to be a summary 11 of what took place at that meeting? 12 A. It looks like somebody wrote this up, but 13 I don't know whom. 14 Q. Again, I would represent to you that this 15 was found in your files. 16 A. Right. But, again, it doesn't say who 17 wrote it -- 18 Q. Correct. 19 A. -- and when it was written. 20 Q. And I'd like to turn your attention to 21 the last three Bates numbers 855, the second to last 22 page under the label of Informative Censoring. 23 A. Yes. 24 Q. Do you see that?</p>	<p>328</p> <p>1 at Searle. 2 Q. And she attended the meetings with the 3 FDA leading up to the advisory committee meeting? 4 A. It depends on which meetings you're 5 talking about because there were several people in 6 regulatory. So I'd have to know specifically which 7 meeting we're referring to. 8 Q. Did she attend that January 26th meeting? 9 A. According to this, she did. 10 Q. I want to show you what I'm marking as 11 Exhibit 275. 12 (WHEREUPON, a certain document was 13 marked Plaintiffs' Deposition 14 Exhibit No. 275, for identification, 15 as of 12/10/2010.) 16 BY MR. SAHAM: 17 Q. I'm going to show you what I'm marking as 18 Plaintiffs' Exhibit 275. 19 Could you please take a look at that 20 document, sir. 21 MR. SAHAM: And for the record, Plaintiffs' 22 Exhibit 275 is a two-page e-mail chain bearing 23 Bates numbers DEFS 00205502 through 503. And the 24 middle e-mail on the page is drafted by you, and</p>



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<p style="text-align: center;">329</p> <p>1 the -- and so is the bottom e-mail on the page is</p> <p>2 also drafted by you. And then the middle e-mail was</p> <p>3 drafted by Dr. Lefkowitz on September 20, 2001, and</p> <p>4 was sent to you and Dr. Verburg. And the subject is</p> <p>5 ACP GI abstract draft.</p> <p>6 BY MR. SAHAM:</p> <p>7 Q. And I ask if you recognize this e-mail</p> <p>8 chain?</p> <p>9 I ask if you recognize this e-mail chain?</p> <p>10 A. I do not.</p> <p>11 Q. Okay. But you don't dispute that you</p> <p>12 received and sent the e-mails as indicated?</p> <p>13 A. I -- I just don't remember these e-mails.</p> <p>14 Q. Okay. And Dr. Lefkowitz writes to you,</p> <p>15 "The question then arises why we didn't go with the</p> <p>16 longer-term data."</p> <p>17 Do you understand what he's talking about</p> <p>18 there?</p> <p>19 A. Where exactly --</p> <p>20 Q. Well, I'm in the middle -- his e-mail in</p> <p>21 the middle. It says, "I can revise the abstract to</p> <p>22 show both analyses, but I am concerned that simply</p> <p>23 showing that the 6-month and longer-term data are</p> <p>24 not different isn't a compelling presentation. The</p>	<p style="text-align: center;">331</p> <p>1 or I'm sorry, G.D. Searle's business operation?</p> <p>2 A. It was -- this was the practice to do a</p> <p>3 separate statistical analysis plan for protocols.</p> <p>4 Q. And like a protocol, it was submitted to</p> <p>5 the FDA?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. And it would be done so in the</p> <p>8 ordinary scope of business at G.D. Searle?</p> <p>9 A. Yes, it would have.</p> <p>10 Q. Okay. I want to show you what I'm</p> <p>11 marking as -- or what's previously been marked in</p> <p>12 this case as Plaintiffs' Exhibit 227.</p> <p>13 Ask you if you recognize this document?</p> <p>14 A. Yes, I do.</p> <p>15 Q. And this is the notice of 30(b)(6)</p> <p>16 deposition, which you're appearing, in part, today</p> <p>17 to testify on certain topics; is that correct?</p> <p>18 A. Yes, it is.</p> <p>19 Q. And with respect to Topic 2, issuance of</p> <p>20 the press release, including, but not limited to,</p> <p>21 the process for an individuals involved with</p> <p>22 drafting, editing and approving the press release,</p> <p>23 you're testifying on behalf of Pharmacia for</p> <p>24 Topic 2?</p>
<p style="text-align: center;">330</p> <p>1 question then arises why we didn't go with the</p> <p>2 longer-term data."</p> <p>3 Do you see that?</p> <p>4 A. I do see that.</p> <p>5 Q. Do you know what he's talking about?</p> <p>6 A. I don't.</p> <p>7 Q. And he's dead, unfortunately, right?</p> <p>8 A. Unfortunately, correct.</p> <p>9 Q. I want to show you what's previously been</p> <p>10 marked as Plaintiffs' Exhibit 110.</p> <p>11 Could you take a look at Plaintiffs'</p> <p>12 Exhibit 110.</p> <p>13 And all I want to ask you about this --</p> <p>14 you've referred before to this statistical analysis</p> <p>15 plan, and this document, Exhibit 110 is labeled a</p> <p>16 plan of the final analyses for Celecoxib - Incidents</p> <p>17 of clinically significant UGI adverse events versus</p> <p>18 Ibuprofen and Diclofenac in OA or RA, and the</p> <p>19 documentation date is December 7th, 1999.</p> <p>20 Is this the statistical analysis plan you</p> <p>21 were referring to earlier?</p> <p>22 A. It appears so, yes.</p> <p>23 Q. Okay. And this is a document that would</p> <p>24 have been created in the ordinary scope of Parm- --</p>	<p style="text-align: center;">332</p> <p>1 A. On page 3?</p> <p>2 Q. Correct.</p> <p>3 A. Yes, I am.</p> <p>4 Q. And with respect to Topic 3, the decision</p> <p>5 to analyze and publish results concerning the first</p> <p>6 six months of data obtained from the CLASS study,</p> <p>7 including, without limitation, identification of</p> <p>8 those individuals who made the decision, when the</p> <p>9 decision was made and any documents or minutes</p> <p>10 memorializing the decision, you're testifying on</p> <p>11 behalf of defendant Pharmacia for that topic, as</p> <p>12 well?</p> <p>13 A. Yes, I am.</p> <p>14 Q. And with respect to Topic 4, the</p> <p>15 individuals responsible for analyzing impact of</p> <p>16 informative censoring or physiological adaptation on</p> <p>17 the CLASS results and any analyses undertaken,</p> <p>18 you're testifying on behalf of Pharmacia for</p> <p>19 Topic 4, as well?</p> <p>20 A. Yes.</p> <p>21 Q. And with respect to Topic 5, drafting,</p> <p>22 review and approval of any presentation made to the</p> <p>23 American College of Physicians on or about</p> <p>24 April 17th, 2000, including, without limitation,</p>



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<p>333</p> <p>1 those individuals involved in the drafting, review 2 and approval process and any documents or minutes 3 memorializing the process, you're testifying on 4 behalf of defendant Pharmacia for Topic 5, as well? 5 A. Yes. 6 Q. Any other topics that you understand 7 you're testifying on behalf of Pharmacia for? 8 A. I believe, as I understand it, those are 9 the ones. 10 Q. Okay. And we're virtually out of time 11 for the deposition today, but I would like to ask 12 you, your -- your lawyers will get a copy of the 13 transcript and then send it to you, and will you 14 review it and make corrections and send whatever 15 corrections or additions you think are appropriate 16 on the errata page back to your counsel in a timely 17 fashion? 18 A. Yes, I will. 19 MR. SAHAM: Okay. With that, I -- 20 MR. WEISS: Can I ask just one follow-up 21 question? 22 MR. SAHAM: Well, then I might have more 23 questions. 24</p>	<p>335</p> <p>1 STATE OF ILLINOIS ) 2 ) SS: 3 COUNTY OF DU PAGE ) 4 I, Nicole Scola, a Notary Public within 5 and for the County of DuPage State of Illinois, and 6 a Certified Shorthand Reporter of said state, do 7 hereby certify: 8 That previous to the commencement of the 9 examination of the witness, the witness was duly 10 sworn to testify the whole truth concerning the 11 matters herein; 12 That the foregoing deposition transcript 13 was reported stenographically by me, was thereafter 14 reduced to typewriting under my personal direction 15 and constitutes a true record of the testimony given 16 and the proceedings had; 17 That the said deposition was taken before 18 me at the time and place specified; 19 That I am not a relative or employee or 20 attorney or counsel, nor a relative or employee of 21 such attorney or counsel for any of the parties 22 hereto, nor interested directly or indirectly in the 23 outcome of this action. 24 IN WITNESS WHEREOF, I do hereunto set my</p>
<p>334</p> <p>1 EXAMINATION 2 BY MR. WEISS: 3 Q. Dr. Geis, earlier today you were asked 4 some questions about whether or not -- in connection 5 with the 30(b)(6) notice and the topic regarding the 6 press release, whether you had reviewed the drafts 7 of the press release -- the press releases in 8 preparation for your deposition, and you testified 9 that you had not; is that correct? 10 A. You know, when I think back on that, I 11 saw them but didn't explicitly go through each one 12 and read each one. But I saw the drafts and that 13 there were drafts, so I'm aware there were drafts 14 before the final. 15 MR. SAHAM: I don't have any additional 16 questions at this time. 17 THE VIDEOGRAPHER: That concludes today's 18 deposition of Steven Geis on December 10, 2010. 19 We're going off the video record at 5:23 p.m. 20 FURTHER DEPONENT SAITH NOT. 21 22 23 24</p>	<p>336</p> <p>1 hand and affix my seal of office at Chicago, 2 Illinois, this 24th day of December, 2010. 3 4 5 Notary Public, DuPage 6 County, Illinois. 7 My commission expires 08/30/2014. 8 9 10 C.S.R. Certificate No. 084-004524. 11 12 13 14 15 16 17 18 19 20 21 22 23 24</p>



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3	WITNESS EXAMINATION
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5	STEVEN GEIS
6	Mr. Saham 5 10
7	Mr. Weiss 334 2
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17	No. 253..... 92 4
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1 DEPOSITION ERRATA SHEET

2 Assignment No. 179917

3 UNITED STATES DISTRICT COURT

4 DISTRICT OF NEW JERSEY

5 ALASKA ELECTRICAL PENSION )

6 FUND, et al., On Behalf of )

7 Themselves and All Others ) No. 03-1519

8 Similarly Situated, ) (AET)

9 Plaintiffs, )

10 vs. )

11 PHARMACIA CORPORATION, et al., )

12 Defendants. )

13 DECLARATION UNDER PENALTY OF PERJURY

14 I declare under penalty of perjury that I

15 have read the entire transcript of my Deposition

16 taken in the captioned matter or the same has been

17 read to me, and the same is true and accurate, save

18 and except for changes and/or corrections, if any,

19 as indicated by me on the DEPOSITION ERRATA SHEET

20 hereof, with the understanding that I offer these

21 changes as if still under oath.

22 Signed on the \_\_\_\_\_ day of

23 \_\_\_\_\_, 20\_\_\_\_.

24 STEVEN GEIS

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1 DEPOSITION ERRATA SHEET

2 Page No. \_\_\_\_\_ Line No. \_\_\_\_\_ Change to: \_\_\_\_\_

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4 Reason for change: \_\_\_\_\_

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22 Reason for change: \_\_\_\_\_

23 SIGNATURE: \_\_\_\_\_ DATE: \_\_\_\_\_

24 STEVEN GEIS

<p style="text-align: center;">341</p> <p>1 DEPOSITION ERRATA SHEET</p> <p>2 Page No. _____ Line No. _____ Change to: _____</p> <p>3 _____</p> <p>4 Reason for change: _____</p> <p>5 Page No. _____ Line No. _____ Change to: _____</p> <p>6 _____</p> <p>7 Reason for change: _____</p> <p>8 Page No. _____ Line No. _____ Change to: _____</p> <p>9 _____</p> <p>10 Reason for change: _____</p> <p>11 Page No. _____ Line No. _____ Change to: _____</p> <p>12 _____</p> <p>13 Reason for change: _____</p> <p>14 Page No. _____ Line No. _____ Change to: _____</p> <p>15 _____</p> <p>16 Reason for change: _____</p> <p>17 Page No. _____ Line No. _____ Change to: _____</p> <p>18 _____</p> <p>19 Reason for change: _____</p> <p>20 Page No. _____ Line No. _____ Change to: _____</p> <p>21 _____</p> <p>22 Reason for change: _____</p> <p>23 SIGNATURE: _____ DATE: _____</p> <p>24 STEVEN GEIS</p>	



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# EXHIBIT 9



De Angelis, Catherine 1/12/2007 11:00:00 AM

<p>1 IN THE UNITED STATES DISTRICT COURT 2 DISTRICT OF NEW JERSEY 3 4 _____ 5 ALASKA ELECTRICAL PENSION FUND, ) 6 et al., on behalf of themselves ) 7 and all others similarly situated,) ) 8 Plaintiffs, ) 9 vs. ) No. 03-1519 10 PHARMACIA CORPORATION, et al., ) 11 Defendants. ) 12 _____) 13 14 Videotaped deposition of CATHERINE 15 DE ANGELIS, at 515 North State Street, 16 Chicago, Illinois, commencing at 17 11:00 a.m. on Friday, January 12, 18 2007, before Donna M. Stifter, RPR, 19 CSR No. 084-003145. 20 21 22 23 24</p>	<p>3 1 APPEARANCES OF COUNSEL: 2 3 FOR THE DEFENDANT PFIZER CORPORATION: 4 DLA PIPER US LLP 5 BY: MR. LOREN H. BROWN 6 1251 Avenue of the Americas 7 New York, New York 10020-1104 8 (212) 335-4846 9 10 11 FOR THE DEPONENT: 12 AMERICAN MEDICAL ASSOCIATION 13 BY: MR. LEONARD A. NELSON 14 515 North State Street 15 Chicago, Illinois 60610 16 (312) 464-5532 17 18 ALSO PRESENT: 19 John Sheehan, Videographer 20 21 22 23 24</p>
<p>2 1 APPEARANCES OF COUNSEL: 2 3 FOR THE PLAINTIFFS: 4 LERACH COUGHLIN STOIA GELLER 5 RUDMAN &amp; ROBBINS, LLP 6 BY: MR. MATTHEW MONTGOMERY 7 655 West Broadway 8 Suite 1900 9 San Diego, California 92101-3301 10 (619) 231-1058 11 12 13 FOR THE DEFENDANT PHARMACIA CORPORATION: 14 CADWALADER, WICKERSHAM &amp; TAFT, LLP 15 BY: MR. JASON M. HALPER 16 MS. KATHERINE A. RITCHIE 17 One World Financial Center 18 New York, New York 10281 19 (212) 504-6605 20 21 22 23 24</p>	<p>4 1 THE VIDEOGRAPHER: Good morning. This 11:08 2 is Videotape No. 1 of the deposition of miss 3 Catherine DeAngelis taken in the matter of Alaska 4 Electrical Pension Fund, et al. vs. Pharmacia 5 Corp., et al., in the United States District Court 11:09 6 for Northern Illinois, Case No. -- 7 MR. MONTGOMERY: New Jersey. 8 THE VIDEOGRAPHER: I'm sorry. District 9 of New Jersey, Case No. 03-1519. 10 This deposition is being held in 11:09 11 the offices of the American Medical Association 12 located at 515 North State Street, Chicago, 13 Illinois. The date today is the 12th day of 14 January, 2007. The time now is approximately 15 11:09. 11:09 16 At this time I'd like the counsels 17 to please identify themselves and whom they 18 represent. 19 MR. MONTGOMERY: Matthew Montgomery from 20 Lerach Coughlin for plaintiffs. 11:09 21 MR. HALPER: Jason Halper, Cadwalader, 22 for the defendants. 23 MR. BROWN: Loren Brown for Pfizer. 24 MS. RITCHIE: Katherine Ritchie of</p>

De Angelis, Catherine 1/12/2007 11:00:00 AM

<p>5</p> <p>1 Cadwalader for defendants. 11:10</p> <p>2 MR. NELSON: Leonard Nelson representing</p> <p>3 the witness.</p> <p>4 THE VIDEOGRAPHER: And I'd just like to</p> <p>5 say that those of you that aren't actually miked 11:10</p> <p>6 up, we can hear everybody very clearly, so there's</p> <p>7 no problem with that.</p> <p>8 At this time I'd like the Court</p> <p>9 Reporter to please administer the oath and we may</p> <p>10 begin. 11:10</p> <p>11 CATHERINE DE ANGELIS,</p> <p>12 having been first duly sworn, was examined and</p> <p>13 testified as follows:</p> <p>14 EXAMINATION</p> <p>15 BY MR. MONTGOMERY: 11:10</p> <p>16 BY MR. MONTGOMERY:</p> <p>17 Q. Could you state your name for the</p> <p>18 record, please?</p> <p>19 A. Catherine DeAngelis.</p> <p>20 Q. Good morning, Dr. DeAngelis. 11:10</p> <p>21 A. Good morning.</p> <p>22 Q. As I told you earlier, my name is Matt</p> <p>23 Montgomery and I represent the plaintiffs in this</p> <p>24 case.</p>	<p>7</p> <p>1 BY MR. MONTGOMERY: 11:11</p> <p>2 Q. First of all, I'd like to thank you for</p> <p>3 being here, and I appreciate your time. My goal</p> <p>4 is to get the information I need and get you out</p> <p>5 of here as quickly as possible. 11:11</p> <p>6 A. Thank you. And you're welcome.</p> <p>7 Q. We're basically going to go through this</p> <p>8 stack of documents. So you can tell where we are</p> <p>9 in the deposition, at least my part of the</p> <p>10 deposition, by how far through it we are. 11:12</p> <p>11 A. Sure.</p> <p>12 Q. Have you ever been deposed before?</p> <p>13 A. Yes, sir.</p> <p>14 Q. How many times, approximately?</p> <p>15 A. Oh, five or six. 11:12</p> <p>16 Q. Okay. Then I'll skip some of the</p> <p>17 preliminaries.</p> <p>18 Do you understand that even though</p> <p>19 we're in a conference room, the oath you just took</p> <p>20 has the same force and effect as it would if you 11:12</p> <p>21 were in a court of law?</p> <p>22 A. Yes.</p> <p>23 Q. And do you understand that the Court</p> <p>24 Reporter to my left and your right is typing down</p>
<p>6</p> <p>1 The plaintiffs in this case at this 11:10</p> <p>2 point are a group of pension funds that bought</p> <p>3 stock in Pharmacia between 2000 and 2002.</p> <p>4 A. Yes.</p> <p>5 Q. And the basis of the case is that they 11:11</p> <p>6 allege that defendants, which are Pharmacia,</p> <p>7 Pfizer, and some of their employees, made false or</p> <p>8 misleading statements about Celebrex and data</p> <p>9 concerning Celebrex during that time.</p> <p>10 A. Okay. 11:11</p> <p>11 Q. So the allegation is that by</p> <p>12 misrepresenting the data regarding Celebrex they</p> <p>13 inflated the value and the price of the Pharmacia</p> <p>14 stock that my clients purchased, and when the</p> <p>15 truth about Celebrex came out, that stock 11:11</p> <p>16 declined.</p> <p>17 A. Okay.</p> <p>18 Q. So the reason that the suit was</p> <p>19 instigated was to try and get that money back. I</p> <p>20 just thought you might appreciate the background. 11:11</p> <p>21 MR. BROWN: For the record, the</p> <p>22 defendants disagree with those allegations.</p> <p>23 MR. MONTGOMERY: That's safe to say.</p> <p>24 THE WITNESS: Okay.</p>	<p>8</p> <p>1 all my questions and your answers, so we can't 11:12</p> <p>2 overlap with one another?</p> <p>3 A. Yes.</p> <p>4 Q. Now, during the course of the deposition</p> <p>5 your attorney or one of the defense attorneys may 11:12</p> <p>6 interpose an objection.</p> <p>7 A. Okay.</p> <p>8 Q. Unless your attorney instructs you not</p> <p>9 to answer, I'd like you to let them get their</p> <p>10 objection on the record and then go ahead and 11:12</p> <p>11 answer.</p> <p>12 A. Okay.</p> <p>13 MR. MONTGOMERY: Counsel, can we all</p> <p>14 agree that an objection made by anyone applies to</p> <p>15 everyone? In other words, if he objects to form, 11:12</p> <p>16 you don't have to make the exact same objection.</p> <p>17 MR. HALPER: Yes.</p> <p>18 BY MR. MONTGOMERY:</p> <p>19 Q. Before we get into the substantive</p> <p>20 questions, I wanted to define a few terms so we 11:13</p> <p>21 can make it easier when we get going.</p> <p>22 Are you familiar with the drug</p> <p>23 celecoxib?</p> <p>24 A. Yes.</p>

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<p>9</p> <p>1 Q. And is its commercial name Celebrex? 11:13</p> <p>2 A. Yes.</p> <p>3 Q. So if I refer to Celebrex, you</p> <p>4 understand I'm also referring to celecoxib?</p> <p>5 A. Yes. 11:13</p> <p>6 Q. Are you familiar with the celecoxib</p> <p>7 long-term arthritis safety study also called</p> <p>8 CLASS?</p> <p>9 A. Yes.</p> <p>10 Q. So if I refer to CLASS, I'd be referring 11:13</p> <p>11 to that study.</p> <p>12 A. I'm familiar at least with the component</p> <p>13 that we dealt with at JAMA.</p> <p>14 Q. JAMA is another example. That is the</p> <p>15 Journal of the American Medical Association; 11:13</p> <p>16 correct?</p> <p>17 A. Yes. But our official name is, our</p> <p>18 legal name is JAMA, the Journal of the American</p> <p>19 Medical Association.</p> <p>20 Q. Okay. I did not know that. 11:14</p> <p>21 As I explained to you earlier, the</p> <p>22 defendants in this case are Pfizer, Pharmacia, and</p> <p>23 certain of their employees. So if I say the</p> <p>24 "defendants," I mean those companies and their</p>	<p>11</p> <p>1 subpoena pursuant to which you're here today? 11:16</p> <p>2 (Document tendered to the witness.)</p> <p>3 A. Yes.</p> <p>4 Q. Have you seen this before?</p> <p>5 A. Yes. 11:16</p> <p>6 Q. I only want to ask you about the last</p> <p>7 page.</p> <p>8 And while we're at it, it's a good</p> <p>9 time to explain: I'm going to show you several</p> <p>10 documents today. Feel free to read all or a part 11:16</p> <p>11 of whichever document I show you. But a lot of</p> <p>12 times I'm only going to be asking you about a</p> <p>13 small part of the document. So you might want to</p> <p>14 let me point you in the direction and then you can</p> <p>15 read as much of the document as you feel is 11:16</p> <p>16 necessary to get the context.</p> <p>17 A. Okay.</p> <p>18 Q. All right. Looking at Page 9 of Exhibit</p> <p>19 17, do you see the items under Documents Requested</p> <p>20 and under Request No. 2, all documents concerning 11:16</p> <p>21 the CLASS study? It says Request No. 2. Do you</p> <p>22 see that?</p> <p>23 A. Yes.</p> <p>24 Q. Did you personally do anything to search</p>
<p>10</p> <p>1 employees. 11:14</p> <p>2 A. Yes.</p> <p>3 MR. HALPER: Just for the sake of</p> <p>4 accuracy, the individuals who are defendants in</p> <p>5 the case are former Pharmacia employees. 11:14</p> <p>6 THE WITNESS: I see.</p> <p>7 MR. MONTGOMERY: At this point I'd like</p> <p>8 to ask the Court Reporter to mark what will be</p> <p>9 Exhibit 17.</p> <p>10 (WHEREUPON Deposition Exhibit 11:15</p> <p>11 No. 17 was marked as of</p> <p>12 1/12/2007.)</p> <p>13 THE VIDEOGRAPHER: While the witness is</p> <p>14 reviewing that, can I ask to go off the record</p> <p>15 just for technical matters for just a couple 11:15</p> <p>16 seconds?</p> <p>17 MR. MONTGOMERY: Sure. Go ahead.</p> <p>18 THE VIDEOGRAPHER: Thank you very much.</p> <p>19 We are going off the record at 11:15.</p> <p>20 (WHEREUPON a recess was taken.) 11:16</p> <p>21 THE VIDEOGRAPHER: We are back on the</p> <p>22 record at 11:15.</p> <p>23 BY MR. MONTGOMERY:</p> <p>24 Q. For the record, Exhibit 17 is the</p>	<p>12</p> <p>1 for or produce documents concerning the CLASS 11:17</p> <p>2 study?</p> <p>3 A. I delegated that responsibility but took</p> <p>4 responsibility for it.</p> <p>5 Q. Who did you delegate it to? 11:17</p> <p>6 A. Various people who had access to them.</p> <p>7 MR. MONTGOMERY: I'd like to ask the</p> <p>8 Court Reporter to mark what will be Exhibit 18.</p> <p>9 (WHEREUPON Deposition Exhibit</p> <p>10 No. 18 was marked as of 11:17</p> <p>11 1/12/2007.)</p> <p>12 BY MR. MONTGOMERY:</p> <p>13 Q. Is this a copy of your Curriculum Vitae?</p> <p>14 (Document tendered to the witness.)</p> <p>15 A. Yes. 11:17</p> <p>16 Q. Do you know if it's current?</p> <p>17 A. It's current as of August 15, 2006.</p> <p>18 Q. Has anything changed on it since that</p> <p>19 time?</p> <p>20 A. A few more publications, one more honor. 11:18</p> <p>21 Q. Do any of the publications concern</p> <p>22 Celebrex?</p> <p>23 A. No.</p> <p>24 Q. If you turn to Page 4 of Exhibit 18,</p>

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<p>13</p> <p>1 please, it indicates towards the top of that page 11:18</p> <p>2 that beginning in the year 2000 you became the</p> <p>3 editor in chief of JAMA; is that correct?</p> <p>4 A. Yes.</p> <p>5 Q. At what point in the year did you 11:18</p> <p>6 become --</p> <p>7 A. January 1st.</p> <p>8 Q. And you still have that position today?</p> <p>9 A. Yes.</p> <p>10 Q. Thinking of the time period of 2000 11:18</p> <p>11 through 2002, what were your responsibilities as</p> <p>12 editor in chief generally speaking?</p> <p>13 A. I was responsible for all editorial</p> <p>14 material that appeared in JAMA related</p> <p>15 specifically to JAMA or anything that appeared 11:19</p> <p>16 on-line.</p> <p>17 Q. From a day-to-day perspective, what were</p> <p>18 your responsibilities with regard to the contents?</p> <p>19 Did you personally edit every article that</p> <p>20 appeared in JAMA? 11:19</p> <p>21 A. Did I personally edit, no. Did I</p> <p>22 personally read and approve every one after</p> <p>23 various people edited, yes.</p> <p>24 Q. We spoke a little earlier about the</p>	<p>15</p> <p>1 you were just talking about? 11:21</p> <p>2 A. Repeat that.</p> <p>3 Q. Sure. Did you have any substantive</p> <p>4 conversations or discussions about the CLASS study</p> <p>5 before the editorial meeting that you just talked 11:21</p> <p>6 about a minute ago?</p> <p>7 A. I might have discussed it with the</p> <p>8 editor who was handling it. But we discuss all</p> <p>9 kinds of things all the time. Our offices are all</p> <p>10 together. 11:21</p> <p>11 Q. Sitting here today, do you remember</p> <p>12 the --</p> <p>13 A. No.</p> <p>14 Q. -- content of those conversations?</p> <p>15 A. No. 11:21</p> <p>16 Q. I appreciate your willingness to answer,</p> <p>17 but you have to make sure and wait until I'm done</p> <p>18 with my question before you answer, just so she</p> <p>19 can type it more easily.</p> <p>20 Okay. You mentioned an editorial 11:21</p> <p>21 meeting though which is the first -- I'm sorry,</p> <p>22 it's not the first time. You mentioned an</p> <p>23 editorial meeting?</p> <p>24 A. Manuscript meeting.</p>
<p>14</p> <p>1 CLASS study. Do you recall that? 11:19</p> <p>2 A. Yes.</p> <p>3 Q. Do you remember the first time you heard</p> <p>4 of the CLASS study?</p> <p>5 A. Probably early in that year. 11:19</p> <p>6 Q. 2000?</p> <p>7 A. Yes.</p> <p>8 Q. How did you hear about it?</p> <p>9 A. Well, first I knew it was in the matrix</p> <p>10 of a submitted manuscript, and then I became more 11:20</p> <p>11 familiar with it when it was discussed at a</p> <p>12 manuscript meeting.</p> <p>13 Q. So the first time you became aware of it</p> <p>14 was after a manuscript had been submitted to JAMA?</p> <p>15 A. Yes, yes. 11:20</p> <p>16 Q. And was that approximately the summer of</p> <p>17 2000?</p> <p>18 A. A little before, spring.</p> <p>19 Q. Who submitted the manuscript to JAMA?</p> <p>20 A. The corresponding author I believe was 11:20</p> <p>21 someone named Lefkowitz. I believe that was his</p> <p>22 name.</p> <p>23 Q. Did you have any substantive discussions</p> <p>24 about the CLASS study prior to the meeting that</p>	<p>16</p> <p>1 Q. I'm sorry, manuscript meeting. And what 11:21</p> <p>2 occurred at that meeting?</p> <p>3 A. The paper was presented by the editor</p> <p>4 who was handling it, it was discussed, and we made</p> <p>5 a deposition about what, a disposition, excuse me, 11:22</p> <p>6 about what we were going to do with it.</p> <p>7 Q. Who is the editor that was in charge of</p> <p>8 the article?</p> <p>9 A. I am in charge of all articles. The one</p> <p>10 who was handling it on a day-to-day basis was 11:22</p> <p>11 Dr. Margaret Winker.</p> <p>12 Q. Who else was at the meeting?</p> <p>13 A. I don't remember.</p> <p>14 Q. Do you remember anyone else specifically</p> <p>15 other than yourself and Dr. Winker? 11:22</p> <p>16 A. No.</p> <p>17 Q. Do you remember any of the discussion</p> <p>18 that occurred at that meeting regarding the CLASS</p> <p>19 study?</p> <p>20 A. Not specifically, no. 11:22</p> <p>21 Q. What was the disposition that resulted</p> <p>22 from that meeting?</p> <p>23 A. Revise and reconsider.</p> <p>24 Q. Do you remember approximately when that</p>

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<p>17</p> <p>1 meeting occurred? 11:23</p> <p>2 A. No.</p> <p>3 Q. After that meeting when was the next</p> <p>4 time you considered the manuscript that had been</p> <p>5 submitted? 11:23</p> <p>6 A. It was discussed again at another</p> <p>7 manuscript meeting after the revisions had been</p> <p>8 made.</p> <p>9 Q. Do you recall what revisions had been</p> <p>10 requested -- 11:23</p> <p>11 A. No.</p> <p>12 Q. -- from the previous meeting?</p> <p>13 Do you recall what the conversation</p> <p>14 was at that second meeting?</p> <p>15 A. Not specifically. 11:23</p> <p>16 Q. Was there a disposition of the</p> <p>17 article --</p> <p>18 A. Yes.</p> <p>19 Q. -- that resulted from that meeting?</p> <p>20 A. Yes. 11:23</p> <p>21 Q. And what was that?</p> <p>22 A. Provisional accept, meaning there were</p> <p>23 certain things that were necessary before we could</p> <p>24 officially accept it.</p>	<p>19</p> <p>1 Q. Did you participate in those 11:25</p> <p>2 discussions?</p> <p>3 A. Some of them.</p> <p>4 Q. Who did you speak with?</p> <p>5 A. Dr. Winker. 11:25</p> <p>6 Q. Do you recall what you guys discussed?</p> <p>7 A. Mostly I wanted to know what were the</p> <p>8 alterations that were requested on the edited copy</p> <p>9 and what were the responses and how to proceed.</p> <p>10 Q. Were you satisfied with the changes that 11:26</p> <p>11 were made?</p> <p>12 A. Yes.</p> <p>13 Q. I'd like to show the witness now what's</p> <p>14 previously been marked as Exhibit 3. (Document</p> <p>15 tendered to the witness.) 11:26</p> <p>16 For the record, this is an article</p> <p>17 from the September 13, 2000 issue of JAMA entitled</p> <p>18 "Gastrointestinal Toxicity With Celecoxib vs.</p> <p>19 Nonsteroidal Anti-inflammatory Drugs for</p> <p>20 Osteoarthritis and Rheumatoid Arthritis. The 11:27</p> <p>21 CLASS Study: A Randomized Controlled Trial."</p> <p>22 Catchy.</p> <p>23 A. Hey, we try our best.</p> <p>24 Q. So is this the article that was</p>
<p>18</p> <p>1 Q. And sitting here today, do you recall 11:24</p> <p>2 why you accepted the article?</p> <p>3 A. Because we thought that it was well</p> <p>4 done, it was well reviewed by peers, they had made</p> <p>5 the changes that we had requested to make it 11:24</p> <p>6 stronger scientifically, and it was one of the</p> <p>7 best of the, at that point I think we had about</p> <p>8 thirty-five hundred to four thousand manuscripts,</p> <p>9 I guess that year about thirty-five hundred, and</p> <p>10 it was part of the relatively few that we chose to 11:24</p> <p>11 publish.</p> <p>12 Q. Was there something about the content of</p> <p>13 it or the subject matter of it specifically that</p> <p>14 you thought warranted publication in JAMA?</p> <p>15 A. It was clinically relevant. 11:24</p> <p>16 Q. What do you mean by that?</p> <p>17 A. That physicians and clinicians and other</p> <p>18 medical researchers could use the information to</p> <p>19 ultimately take better care of patients.</p> <p>20 Q. After the second meeting that you just 11:25</p> <p>21 described, were there any further meetings prior</p> <p>22 to the article's publication concerning that</p> <p>23 particular article?</p> <p>24 A. Not meetings, no. Discussions.</p>	<p>20</p> <p>1 ultimately published in JAMA concerning the CLASS 11:27</p> <p>2 study?</p> <p>3 A. Yes.</p> <p>4 Q. Do you see the individuals listed on the</p> <p>5 left-hand side of the first page of Exhibit 3? 11:27</p> <p>6 A. Yes.</p> <p>7 Q. Who are they relative to this article?</p> <p>8 A. These are the authors.</p> <p>9 Q. And does the order of the authors as</p> <p>10 they are listed here have any significance? 11:27</p> <p>11 A. Usually the first author is called the</p> <p>12 primary author.</p> <p>13 Q. The first person listed on the list you</p> <p>14 mean?</p> <p>15 A. Dr. Silverstein. 11:28</p> <p>16 Q. Okay.</p> <p>17 A. But in this case the corresponding</p> <p>18 author was third from the last, James Lefkowitz.</p> <p>19 On occasion, depending, usually the</p> <p>20 last author is the senior author but not 11:28</p> <p>21 necessarily.</p> <p>22 Q. What's the difference between a lead</p> <p>23 author and a corresponding author?</p> <p>24 A. The lead author is the first author.</p>

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<p>21</p> <p>1 Q. Okay. 11:28</p> <p>2 A. That's the person who is considered to</p> <p>3 be the first person you would call if you had a</p> <p>4 question about the article once it's published,</p> <p>5 someone in the audience who would read it. 11:28</p> <p>6 The corresponding author is the</p> <p>7 individual with whom we, the editors, correspond</p> <p>8 regarding the manuscript it testify. He</p> <p>9 represents the group.</p> <p>10 Q. What is the participation of all the 11:29</p> <p>11 other people that are listed?</p> <p>12 A. Every one of them have to meet our</p> <p>13 criteria as far as having had a major role in this</p> <p>14 study and they have a signed document to that</p> <p>15 effect, we have that document. 11:29</p> <p>16 Q. Okay. I'd like you to put that aside,</p> <p>17 but we're going to come back to it, so you might</p> <p>18 want to keep it handy.</p> <p>19 MR. MONTGOMERY: I'd like to ask the</p> <p>20 Court Reporter to mark what will be Exhibit 19. 11:29</p> <p>21 (WHEREUPON Deposition Exhibit</p> <p>22 No. 19 was marked as of</p> <p>23 1/12/2007.)</p> <p>24</p>	<p>23</p> <p>1 of numbers there? Those are what we call Bates 11:34</p> <p>2 numbers.</p> <p>3 A. Yes.</p> <p>4 Q. So in other longer documents I may</p> <p>5 direct you and I will usually do it by the Bates 11:34</p> <p>6 number there, and often times I'll just use the</p> <p>7 last three or four digits instead of reading the</p> <p>8 entire thing.</p> <p>9 A. Okay.</p> <p>10 Q. On the second page of Exhibit 19, do you 11:34</p> <p>11 see there's a number of bullet points there?</p> <p>12 A. Yes.</p> <p>13 Q. I'd like you to look at the last bullet</p> <p>14 point that starts "In discussing the CLASS trial."</p> <p>15 And underneath that there's a series of dashes. 11:34</p> <p>16 Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. I'd like you to look at the first one.</p> <p>19 It says "In making the case for publication in</p> <p>20 JAMA, the investigators stated this was a 11:34</p> <p>21 twelve-month study but they only had six months of</p> <p>22 data." Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. Do you remember saying that in --</p>
<p>22</p> <p>1 BY MR. MONTGOMERY: 11:29</p> <p>2 Q. Have you ever seen Exhibit 19 before?</p> <p>3 (Document tendered to the witness.)</p> <p>4 A. No.</p> <p>5 Q. For the record, it's a memo on Ruder 11:32</p> <p>6 Finn stationery dated November 1, 2001, from</p> <p>7 Elinore White to Debra Charlesworth concerning</p> <p>8 remarks by Catherine DeAngelis at a Columbia</p> <p>9 Alliance for Healthcare Management meeting dated</p> <p>10 10/27/01. 11:33</p> <p>11 Do you know what the Columbia</p> <p>12 Alliance for Healthcare Management is?</p> <p>13 A. I don't recall, no.</p> <p>14 Q. Do you recall making a presentation in</p> <p>15 or around 10/27/01 concerning the subject matter 11:33</p> <p>16 of this memo?</p> <p>17 A. Could well be. I've made so many of</p> <p>18 these presentations.</p> <p>19 Q. Do you know who either Debra</p> <p>20 Charlesworth or Elinore White are? 11:33</p> <p>21 A. No.</p> <p>22 Q. Would you turn to the second page of</p> <p>23 Exhibit 19. Also I'd like to point out, do you</p> <p>24 see in the lower right-hand corner there's a set</p>	<p>24</p> <p>1 A. No. 11:35</p> <p>2 Q. -- a presentation?</p> <p>3 A. No. And I would be surprised if I said</p> <p>4 that.</p> <p>5 Q. Why's that? 11:35</p> <p>6 A. Because the investigators, to my</p> <p>7 knowledge, and certainly not to me, never said it</p> <p>8 was a twelve-month study.</p> <p>9 Q. What did they say?</p> <p>10 A. They said that the goal was to get six 11:35</p> <p>11 months data, that some of the participants will</p> <p>12 follow, it was their own decision whether or not</p> <p>13 they wanted to remain in the study longer if they</p> <p>14 wanted to.</p> <p>15 Q. Let's just wait until the siren goes by. 11:35</p> <p>16 MR. BROWN: Just because of the sirens,</p> <p>17 could you read back the last answer?</p> <p>18 (WHEREUPON said record was read</p> <p>19 back as requested.)</p> <p>20 BY MR. MONTGOMERY: 11:36</p> <p>21 Q. So it was represented to you, just</p> <p>22 trying to rephrase, it was represented to you that</p> <p>23 the CLASS study was designed to be a six-month</p> <p>24 study but that some people may have been</p>

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<p>25</p> <p>1 participating longer? 11:36</p> <p>2 A. Yes.</p> <p>3 Q. All right. Would you look at the fourth</p> <p>4 dash underneath that bullet point. I'll read it</p> <p>5 into the record. It says "In February, 11:37</p> <p>6 Dr. DeAngelis said she received a call from a</p> <p>7 colleague informing her that the twelve-month data</p> <p>8 was posted at the FDA website." Is that correct?</p> <p>9 MR. HALPER: Well, objection. Are you</p> <p>10 asking Dr. DeAngelis if she recalls making this 11:37</p> <p>11 statement or sitting here today if she agrees with</p> <p>12 the statement?</p> <p>13 MR. MONTGOMERY: Good objection.</p> <p>14 BY MR. MONTGOMERY:</p> <p>15 Q. Do you recall making that statement? 11:37</p> <p>16 A. Not specifically, no.</p> <p>17 Q. In fact, did that occur? Did you</p> <p>18 receive a call in February?</p> <p>19 A. I can't recall if it was in February,</p> <p>20 but I did receive a call. 11:37</p> <p>21 Q. And who did you receive the call from?</p> <p>22 A. I don't, it says "colleague." I don't</p> <p>23 recall who it was.</p> <p>24 Q. You recall generally speaking though you</p>	<p>27</p> <p>1 had been misled? 11:38</p> <p>2 A. Yes.</p> <p>3 Q. And why did you conclude that?</p> <p>4 A. Because when we asked the question of</p> <p>5 the corresponding author do you have more than six 11:39</p> <p>6 months data, the response, and I don't have it</p> <p>7 here with me, but the correspondence from him via</p> <p>8 Dr. Winker said this is a six-month study and made</p> <p>9 no mention that there were more data. He said the</p> <p>10 study is closed. Those are specific words I 11:39</p> <p>11 remember, the study is closed, and it was a</p> <p>12 six-month study.</p> <p>13 Q. Going back to this document, on that</p> <p>14 bullet point, the last dash says, and I'll read it</p> <p>15 into the record again, "She stated that the 11:39</p> <p>16 pharmaceutical companies involved requested five</p> <p>17 meetings with her. She allowed one meeting and</p> <p>18 they came to an agreement."</p> <p>19 Do you recall saying that at any</p> <p>20 time? 11:40</p> <p>21 A. No.</p> <p>22 Q. Did, in fact, the pharmaceutical</p> <p>23 companies involved ask for a meeting with you?</p> <p>24 A. The pharmaceutical company did request a</p>
<p>26</p> <p>1 received a call -- 11:37</p> <p>2 A. Yes.</p> <p>3 Q. -- from a colleague concerning this</p> <p>4 matter?</p> <p>5 A. Yes. 11:37</p> <p>6 Q. And according to this bullet point, it</p> <p>7 says that that person explained to you that twelve</p> <p>8 months of data was posted on the FDA website.</p> <p>9 Is that what occurred in the call</p> <p>10 that you remember? 11:38</p> <p>11 A. Yes.</p> <p>12 Q. Did the colleague that called you tell</p> <p>13 you anything else that you can remember?</p> <p>14 A. Not really, no. That was the main</p> <p>15 reason he called. I do remember it was a he. 11:38</p> <p>16 Q. All right. Going back to the document,</p> <p>17 the next sentence says "After confirming this, she</p> <p>18 determined she had been misled about the</p> <p>19 availability of the twelve-month data."</p> <p>20 Do you recall saying that at any 11:38</p> <p>21 conference in 2001?</p> <p>22 A. I don't recall saying that, but it's not</p> <p>23 inaccurate.</p> <p>24 Q. So you in fact did determine that you</p>	<p>28</p> <p>1 meeting, yes. 11:40</p> <p>2 Q. Did they request five meetings?</p> <p>3 A. No.</p> <p>4 Q. And did you, in fact, meet with them?</p> <p>5 A. Yes. 11:40</p> <p>6 Q. Do you remember who you met with?</p> <p>7 A. These are the cards. Dr. Michael</p> <p>8 Friedman, who was senior vice president for</p> <p>9 Pharmacia, and Dr. Kenneth Verburg, who's the</p> <p>10 clinical vice president for Pharmacia. (Document 11:40</p> <p>11 tendered to counsel.)</p> <p>12 MR. MONTGOMERY: I'd like to ask the</p> <p>13 Court Reporter to now mark what will be Exhibit</p> <p>14 20. And I'd like the record reflect that the</p> <p>15 witness was just reading from Exhibit 20 reciting 11:41</p> <p>16 those names.</p> <p>17 (WHEREUPON Deposition Exhibit</p> <p>18 No. 20 was marked as of</p> <p>19 1/12/2007.)</p> <p>20 BY MR. MONTGOMERY: 11:41</p> <p>21 Q. Can you tell me what occurred at that</p> <p>22 meeting?</p> <p>23 A. Not specifically, no. I can tell you</p> <p>24 when it occurred.</p>



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<p>29</p> <p>1 Q. When was that? August 21st? 11:41</p> <p>2 A. August 21, 2001.</p> <p>3 Q. On Exhibit 20 in the upper left-hand</p> <p>4 corner there's your name and another doctor</p> <p>5 underneath you. 11:41</p> <p>6 A. Dr. Fontanarosa. He's my executive</p> <p>7 deputy editor. I wanted him in the room with me.</p> <p>8 Q. Why's that?</p> <p>9 A. Because it's a precautionary thing I</p> <p>10 always do. 11:42</p> <p>11 Q. Precautionary against what?</p> <p>12 A. Because my memory is only the memory of</p> <p>13 one brain. It helps to have two, or more. But I</p> <p>14 like him in the room.</p> <p>15 Q. Exhibit 19 references an agreement, that 11:42</p> <p>16 you came to an agreement. Did that actually</p> <p>17 occur?</p> <p>18 A. I'm sorry? We came to an agreement?</p> <p>19 Q. Right. Was there any agreement reached</p> <p>20 at the meeting? 11:42</p> <p>21 A. An agreement to what?</p> <p>22 Q. That was my next question.</p> <p>23 A. No. I don't know what the meaning of</p> <p>24 "agreement" means.</p>	<p>31</p> <p>1 Q. Yes. 11:44</p> <p>2 A. No. I personally did not correspond</p> <p>3 with Dr. Lefkowitz. Dr. Winker did. But when my</p> <p>4 editors correspond, they really, everything comes</p> <p>5 across my name and I take responsibility for it. 11:44</p> <p>6 So anything out of the ordinary they discuss with</p> <p>7 me.</p> <p>8 So while I never directly discussed</p> <p>9 this with Dr. Lefkowitz, I was aware of what was</p> <p>10 going on. I never directly discussed anything 11:44</p> <p>11 with Dr. Silverstein, but he did receive the</p> <p>12 letter from my letter editor over my name</p> <p>13 requesting that he reply.</p> <p>14 Q. And was that prior to the August 21,</p> <p>15 2001 meeting? 11:45</p> <p>16 A. Yes.</p> <p>17 Q. Prior to the August 21, 2001 meeting, to</p> <p>18 your knowledge, did anyone from JAMA communicate</p> <p>19 with anyone from Pharmacia or Pfizer concerning</p> <p>20 the JAMA article? 11:45</p> <p>21 A. Not to my knowledge.</p> <p>22 Q. Do you have an understanding why at this</p> <p>23 time, August 21, 2001, you were communicating with</p> <p>24 the company as opposed to the authors of the</p>
<p>30</p> <p>1 We had a discussion, and he 11:42</p> <p>2 understood, I made him understand why I was upset.</p> <p>3 The reason he had called was because we had sent</p> <p>4 letters that we received from people making</p> <p>5 essentially the same allegation that was said 11:43</p> <p>6 here.</p> <p>7 When people call and have comments</p> <p>8 about a particular article, I invite them to</p> <p>9 please write a letter to the editor and then I ask</p> <p>10 the author to reply. This is the scientific way. 11:43</p> <p>11 There were two letters that we</p> <p>12 received. I sent them to Dr. Silverstein, the</p> <p>13 primary author, and asked for his reply.</p> <p>14 That I believe is what stimulated</p> <p>15 the company calling me, once that I recall. And I 11:43</p> <p>16 just said to them that there would be every</p> <p>17 opportunity for Dr. Silverstein to respond to the</p> <p>18 allegations made in the letters to the editor. If</p> <p>19 you call that an agreement --</p> <p>20 Q. Prior to the meeting that we're talking 11:44</p> <p>21 about, had you only communicated with the</p> <p>22 corresponding author, which was I believe</p> <p>23 Dr. Lefkowitz, concerning the article?</p> <p>24 A. Me personally?</p>	<p>32</p> <p>1 article? 11:45</p> <p>2 A. It was the first question, I do remember</p> <p>3 this specifically, it was the first question I</p> <p>4 asked Dr. Friedman because I fully expected that</p> <p>5 Dr. Silverstein would be in the meeting and he was 11:46</p> <p>6 not.</p> <p>7 Q. And what was the answer to your</p> <p>8 question?</p> <p>9 A. They didn't think it was necessary.</p> <p>10 Q. How did you feel about that response? 11:46</p> <p>11 A. I thought it peculiar.</p> <p>12 Q. Why is that?</p> <p>13 A. Because their concern was about the</p> <p>14 study and neither of these individuals names was</p> <p>15 an author. They didn't partake in this study. So 11:46</p> <p>16 it was a little bit peculiar. It was unusual.</p> <p>17 But I should say it's unusual for me to meet with</p> <p>18 anyone about an article after it's published.</p> <p>19 Q. Right. I should have mentioned earlier:</p> <p>20 If you want to take a break at any time, just let 11:47</p> <p>21 me know and we'll go off the record.</p> <p>22 THE VIDEOGRAPHER: Counsel, could we</p> <p>23 take a break for just a technical matter?</p> <p>24 MR. MONTGOMERY: Sure.</p>

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<p>33</p> <p>1 THE VIDEOGRAPHER: Just a moment. 11:47 2 (WHEREUPON a recess was taken.) 3 THE VIDEOGRAPHER: Okay. We are back on 4 the record. The time now is 11:50. 5 (WHEREUPON Deposition Exhibit 11:50 6 No. 21 was marked as of 7 1/12/2007.) 8 BY MR. MONTGOMERY: 9 Q. I had previously asked the Court 10 Reporter to mark what would be Exhibit 21, which I 11:50 11 believe you now have in front of you; is that 12 correct? Is that correct? You have Exhibit 21 in 13 front of you? (Document tendered to the witness.) 14 A. Yes. 15 Q. Have you ever seen this document before? 11:50 16 A. No. 17 Q. Does it purport to be a final report of 18 the CLASS study? 19 A. Yes. 20 Q. Have you seen final study reports before 11:51 21 of other studies? 22 A. Yes. 23 Q. Does this look more or less like they 24 usually look?</p>	<p>35</p> <p>1 referring to Exhibit 3 throughout the deposition 11:52 2 as just "the JAMA article." 3 Had you been told that, would you 4 have understood that the study lasted longer than 5 six months? 11:52 6 A. Had I been told this, yes. 7 Q. I'd like you to now look down at the 8 section entitled Number of Patients. Do you see 9 that? 10 A. Yes. 11:53 11 Q. The second sentence in that beginning "A 12 total 8,059." Do you see that? 13 A. Yes. 14 Q. I'm going to read that into the record. 15 It says "A total of 8,059 patients were enrolled, 11:53 16 of whom 4,573 completed six months of treatment 17 and 3,409 completed the study." 18 Do you know whether or not you were 19 told that -- 20 A. I was not. 11:53 21 Q. -- prior to publication of the JAMA 22 article? 23 A. No. 24 Q. And had you been told that, would you</p>
<p>34</p> <p>1 A. Yes. 11:51 2 Q. What's the date of this document? It's 3 on the first page, in the middle. 4 A. The dates, September 23, 1998 through 5 March 17, 2000. The document date is the 25th of 11:51 6 May, 2000. 7 Q. Would you turn to the third page, which 8 is Bates number ending 925. Do you see the 9 Methodology section in the middle of the page? 10 A. Yes. 11:52 11 Q. I'd like you to look at the fifth line 12 down in that, beginning "Treatment duration." Do 13 you see that? 14 A. Yes I see it. 15 Q. I'm going to read it into the record. 11:52 16 It says "Treatment duration lasted for at least 17 twenty-six weeks with a maximum potential 18 treatment period of fifty-two or sixty-five 19 weeks." Do you see that? 20 A. Yes. 11:52 21 Q. Were you told that prior to the 22 publication of the JAMA article? 23 A. No. 24 Q. As a point of reference, I'm going to be</p>	<p>36</p> <p>1 have understood that the study lasted longer than 11:53 2 six months? 3 A. Well, yes. 4 Q. You're reaching for Exhibit 3, which is 5 exactly what I'd like you to look at now, if you 11:53 6 would, please. I would like to compare the 7 language that we just looked at with the language 8 on Exhibit 3, on the first page under Participants 9 on the first page of Exhibit 3 of the JAMA 10 article. 11:54 11 A. Right. 12 Q. The last sentence reads "A total of 13 4,573 patients (fifty-seven percent) received 14 treatment for six months." Do you see that? 15 A. Yes. 11:54 16 Q. Now, reading that, did you understand 17 that the study only lasted six months? 18 A. Yes. 19 Q. Had defendants included -- I'm sorry. 20 Had the authors included the language concerning 11:54 21 the number of patients that finished the study, as 22 they did in their final report, would you have 23 understood that the study lasted longer than six 24 months?</p>

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<p>37</p> <p>1 A. Yes. 11:54</p> <p>2 Q. Do you have any understanding of why the</p> <p>3 language from the final report was not used in the</p> <p>4 JAMA article?</p> <p>5 A. I have their explanation. 11:55</p> <p>6 Q. And what was that?</p> <p>7 A. It's what's published in their reply to</p> <p>8 the letters.</p> <p>9 Q. In their letter that was published in</p> <p>10 JAMA? 11:55</p> <p>11 A. The authors in reply response to the two</p> <p>12 letters to the editor stating that there was</p> <p>13 information about twelve months because that's the</p> <p>14 amount of time it took to get the endpoint which</p> <p>15 was really forty gastrointestinal bleeding 11:55</p> <p>16 episodes, which was the real response they were</p> <p>17 looking for, and it took I believe sixty some</p> <p>18 weeks to do that.</p> <p>19 Q. We're going to look at that letter later</p> <p>20 on. But just in general, did you find that 11:56</p> <p>21 explanation satisfactory?</p> <p>22 A. The one by Dr. Silverstein in reply?</p> <p>23 Q. Yes.</p> <p>24 A. I found it satisfactory in response to</p>	<p>39</p> <p>1 Do you see towards the top there's an e-mail 11:59</p> <p>2 saying "Dear All, please find attached two draft</p> <p>3 CLASS manuscripts," et cetera?</p> <p>4 A. Yes.</p> <p>5 Q. Then I'd like you to look at the first 11:59</p> <p>6 page which is a continuing e-mail chain. Do you</p> <p>7 see the second paragraph in the exhibit starting</p> <p>8 "In my opinion"?</p> <p>9 A. Yes.</p> <p>10 Q. I'd like you to look at the second 11:59</p> <p>11 sentence in that. It says "We are also</p> <p>12 cherry-picking the data (using six months as study</p> <p>13 duration)."</p> <p>14 Are you familiar with the phrase</p> <p>15 "cherry-picking"? 12:00</p> <p>16 A. Quite.</p> <p>17 Q. What's your understanding of the phrase?</p> <p>18 A. You choose the best looking cherries.</p> <p>19 Q. And in your experience is cherry-picking</p> <p>20 data appropriate in the context of a manuscript 12:00</p> <p>21 concerning a medical study?</p> <p>22 A. No.</p> <p>23 Q. Prior to the publication of the JAMA</p> <p>24 article, did the defendants tell you that they</p>
<p>38</p> <p>1 the two letters. It provided information for the 11:56</p> <p>2 readers, the clinicians and scientists, to know</p> <p>3 what to make of this study.</p> <p>4 Q. Did you think that their explanation</p> <p>5 justified the representations that were made to 11:56</p> <p>6 JAMA concerning the length of the study?</p> <p>7 A. If you will look at the reply that</p> <p>8 Dr. Silverstein made, he specifically states, or</p> <p>9 he and the authors who signed it, "In retrospect</p> <p>10 we should have," and I don't want to paraphrase 11:57</p> <p>11 him because you have what he said.</p> <p>12 Q. Sure. Okay.</p> <p>13 MR. MONTGOMERY: I'd like to ask the</p> <p>14 Court Reporter to mark what will be Exhibit 22.</p> <p>15 (WHEREUPON Deposition Exhibit 11:58</p> <p>16 No. 22 was marked as of</p> <p>17 1/12/2007.)</p> <p>18 BY MR. MONTGOMERY:</p> <p>19 Q. For the record, Exhibit 22 is an e-mail</p> <p>20 chain, the top e-mail of which is from Mona Wahba, 11:58</p> <p>21 W-A-H-B-A, to Stephen Cristo, C-R-I-S-T-O, dated</p> <p>22 May 22, 2001. (Document tendered to the witness.)</p> <p>23 I'd like you to start looking at</p> <p>24 the second page of Exhibit 22, Bates ending 696.</p>	<p>40</p> <p>1 were cherry-picking the first six months of data 12:01</p> <p>2 from the study?</p> <p>3 MR. HALPER: Objection to the form.</p> <p>4 MR. NELSON: You should answer the</p> <p>5 question. 12:01</p> <p>6 THE WITNESS: No. They didn't tell me.</p> <p>7 BY MR. MONTGOMERY:</p> <p>8 Q. Subsequent to the publication of the</p> <p>9 JAMA article, did defendants ever admit to you</p> <p>10 that they had cherry-picked the first six months 12:01</p> <p>11 of data from the CLASS study?</p> <p>12 MR. HALPER: Object to form.</p> <p>13 THE WITNESS: No.</p> <p>14 MR. MONTGOMERY: He's just putting his</p> <p>15 objections on the record. You can go ahead and 12:01</p> <p>16 answer them, unless your attorney instructs you</p> <p>17 not to.</p> <p>18 MR. NELSON: That's correct. But if you</p> <p>19 don't understand the question, you can certainly</p> <p>20 ask that it be rephrased. 12:01</p> <p>21 THE WITNESS: No, I understood. Thank</p> <p>22 you.</p> <p>23 BY MR. MONTGOMERY:</p> <p>24 Q. I'd like to go back to Exhibit 3.</p>

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<p style="text-align: right;">41</p> <p>1 We discussed before the sentence 12:02</p> <p>2 under Participants.</p> <p>3 A. Yes.</p> <p>4 Q. Let's just say the Participant section</p> <p>5 on the first page. 12:02</p> <p>6 Is it correct that having read</p> <p>7 that, you did not understand that the study lasted</p> <p>8 longer than six months?</p> <p>9 A. Reading this, no, you would not</p> <p>10 understand. 12:02</p> <p>11 Q. And you did not at the time of the</p> <p>12 publication of this article; is that correct?</p> <p>13 A. The study, right, I did not know that</p> <p>14 the study went on for more than six months. I</p> <p>15 understood that patients could continue at their 12:02</p> <p>16 own discretion if they wanted to beyond six</p> <p>17 months.</p> <p>18 Q. All right. I'd like to ask you to look</p> <p>19 at the second page of Exhibit 3, Bates No. 879.</p> <p>20 Do you see in the middle of the 12:03</p> <p>21 page there's a heading called Study Protocol?</p> <p>22 A. Yes.</p> <p>23 Q. And there's a paragraph right underneath</p> <p>24 that. I'd like you to look at the last two</p>	<p style="text-align: right;">43</p> <p>1 beginning with "Homogeneity" through the end of 12:04</p> <p>2 that page.</p> <p>3 You can continue reading but that's</p> <p>4 all I needed you to read. Was there anything in</p> <p>5 what you just read from Page 880 of Exhibit 3 that 12:05</p> <p>6 indicated to you that the CLASS study lasted</p> <p>7 longer than six months?</p> <p>8 A. No.</p> <p>9 Q. I'd like to now show the witness what's</p> <p>10 previously been marked Exhibit 8. (Document 12:05</p> <p>11 tendered to the witness.)</p> <p>12 For the record, this is a copy of a</p> <p>13 Washington Post article dated August 5, 2001</p> <p>14 headline "Missing Data On Celebrex; Full Study</p> <p>15 Altered Picture Of Drug." 12:06</p> <p>16 Have you seen this article before?</p> <p>17 A. Yes.</p> <p>18 Q. Did you see it when it was originally</p> <p>19 published?</p> <p>20 A. Yes. 12:07</p> <p>21 Q. How did you feel about it when you read</p> <p>22 it when it was originally published?</p> <p>23 A. Terrible.</p> <p>24 Q. Why is that?</p>
<p style="text-align: right;">42</p> <p>1 sentences of that paragraph, and I'm going to read 12:03</p> <p>2 them into the record. It says "After a baseline</p> <p>3 visit, follow-up clinic visits took place at Weeks</p> <p>4 4, 13, and 26 after the initial dose of</p> <p>5 medication, and every thirteen weeks thereafter. 12:03</p> <p>6 All patients were provided an opportunity to</p> <p>7 complete a minimum of six months of treatment."</p> <p>8 Did you read this portion of the</p> <p>9 article before it was published?</p> <p>10 A. Yes. 12:03</p> <p>11 Q. And having read that, did you understand</p> <p>12 that the study lasted more than six months?</p> <p>13 A. No. I was specifically told it didn't.</p> <p>14 Q. And there's nothing about what I just</p> <p>15 read that was inconsistent with what you were 12:04</p> <p>16 told; is that correct?</p> <p>17 A. Correct.</p> <p>18 Q. Please look at the third page of Exhibit</p> <p>19 3, ending Bates No. 880. So there are three</p> <p>20 columns. I'd like you to look at the last 12:04</p> <p>21 paragraph in the middle column starting</p> <p>22 "Homogeneity."</p> <p>23 This is too long to read into the</p> <p>24 record. Would you please read to yourself</p>	<p style="text-align: right;">44</p> <p>1 A. Because I think it exposed the naivety 12:07</p> <p>2 of some of us who put trust in people who didn't</p> <p>3 deserve that trust, and it made me feel very bad</p> <p>4 that in that trust I had exposed Wolfe, who wrote</p> <p>5 the editorial, to something that I prefer that I 12:08</p> <p>6 hadn't asked him to do.</p> <p>7 Q. Who did you think it made look naive?</p> <p>8 A. I felt naive. Fool me once.</p> <p>9 Q. And who had you put your trust in that</p> <p>10 you wish you had not? 12:08</p> <p>11 A. The authors.</p> <p>12 Q. That's the authors of the JAMA article?</p> <p>13 A. Yes.</p> <p>14 Q. Looking at the first page of Exhibit 8,</p> <p>15 in the middle of the page there's a quote from 12:09</p> <p>16 you. I'd like to read it into the record. It</p> <p>17 says "I am disheartened to hear that they had</p> <p>18 those data at the time that they submitted the</p> <p>19 manuscript to us. We are functioning on a level</p> <p>20 of trust that was perhaps broken." 12:09</p> <p>21 Do you recall saying that?</p> <p>22 A. Yes.</p> <p>23 Q. Do you still agree with what you said</p> <p>24 there?</p>

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<p>45</p> <p>1 A. Yes. 12:09</p> <p>2 Q. I'd like you to look at the second page</p> <p>3 of Exhibit 8. Do you see at the top of that page,</p> <p>4 this is one of the authors of the article,</p> <p>5 Dr. Geis, is quoted as saying "The intention 12:09</p> <p>6 really was not to be deceptive in any way." Do</p> <p>7 you see that?</p> <p>8 A. Yes.</p> <p>9 Q. Sitting here today --</p> <p>10 MR. HALPER: I'm going to object and ask 12:10</p> <p>11 that you read into the record the prior sentence</p> <p>12 which he also is quoted as saying.</p> <p>13 MR. MONTGOMERY: All right. Well, I'm</p> <p>14 not going to, but you're welcome to when you have</p> <p>15 questions. 12:10</p> <p>16 MR. HALPER: Okay.</p> <p>17 BY MR. MONTGOMERY:</p> <p>18 Q. I'll read it again. "The intention</p> <p>19 really was not to be deceptive in any way." Do</p> <p>20 you see that? 12:10</p> <p>21 A. Yes.</p> <p>22 Q. Sitting here today, do you believe that</p> <p>23 to be true?</p> <p>24 A. No.</p>	<p>47</p> <p>1 CATHERINE DE ANGELIS, 12:12</p> <p>2 having been previously duly sworn, was examined</p> <p>3 and testified further as follows:</p> <p>4 EXAMINATION</p> <p>5 (Resumed) 12:12</p> <p>6 BY MR. MONTGOMERY:</p> <p>7 THE VIDEOGRAPHER: Good afternoon. This</p> <p>8 begins Videotape No. 2 of the deposition of</p> <p>9 Catherine DeAngelis. This is Case No. 03-1519 on</p> <p>10 the 12th of January, 2007. The time now is 01:14</p> <p>11 1:14 p.m., and I will remind the witness she</p> <p>12 remains under oath.</p> <p>13 MR. MONTGOMERY: I'd like to ask the</p> <p>14 Court Reporter to mark what will be Exhibit 23.</p> <p>15 (WHEREUPON Deposition Exhibit 01:14</p> <p>16 No. 23 was marked as of</p> <p>17 1/12/2007.)</p> <p>18 BY MR. MONTGOMERY:</p> <p>19 Q. You can read the whole thing if you</p> <p>20 want. I'm only going to ask you about your quote 01:16</p> <p>21 on the third page. So it's up to you. And I</p> <p>22 apologize for the highlighting. (Document</p> <p>23 tendered to the witness.)</p> <p>24 Do you see the quote from you on</p>
<p>46</p> <p>1 MR. MONTGOMERY: All right. Let's go 12:10</p> <p>2 off the record.</p> <p>3 THE VIDEOGRAPHER: Okay. This will</p> <p>4 conclude Videotape No. 1. We are going off the</p> <p>5 record at approximately 12:10. The deposition 12:11</p> <p>6 will continue on Videotape No. 2.</p> <p>7 (WHEREUPON a lunch recess was</p> <p>8 taken, and said deposition</p> <p>9 continued as follows:)</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>48</p> <p>1 the third page Bates number ending 870? 01:16</p> <p>2 A. Yes.</p> <p>3 Q. And it says "I was very upset when I</p> <p>4 found out that they had a full year's data." Do</p> <p>5 you recall saying that? 01:16</p> <p>6 A. Yes.</p> <p>7 Q. Is that an accurate quote?</p> <p>8 A. Yes.</p> <p>9 Q. Before that it paraphrase you saying</p> <p>10 that you told the reporters "the company's study 01:16</p> <p>11 authors should have told her," meaning you, "about</p> <p>12 the extra data and allowed The Journal to decide</p> <p>13 just what to publish."</p> <p>14 Did you tell the reporter basically</p> <p>15 that same thing? 01:17</p> <p>16 A. Yes.</p> <p>17 Q. And do you still agree with that?</p> <p>18 A. Yes.</p> <p>19 Q. I show the witness now what's previously</p> <p>20 been marked as Exhibit 10. (Document tendered to 01:17</p> <p>21 the witness.)</p> <p>22 Once again, I'm just going to ask</p> <p>23 you about your quote on the second page, second</p> <p>24 paragraph, but you're welcome to read the whole</p>

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<p>49</p> <p>1 thing if you'd like. 01:17</p> <p>2 A. Let me put it in context.</p> <p>3 Q. Sure. For the record, this is a</p> <p>4 transcript of an interview from WNBC-TV in New</p> <p>5 York City. 01:18</p> <p>6 A. Yes.</p> <p>7 Q. I'd like to direct you to the second</p> <p>8 page, Bates number ending 653. The second</p> <p>9 paragraph at the top of the page has a quote from</p> <p>10 you. It says "If they had twelve months of data 01:18</p> <p>11 and didn't tell me, I'm going to be very upset.</p> <p>12 If we cannot have a level of trust in the</p> <p>13 investigators, we might as well pack it in." Do</p> <p>14 you see that?</p> <p>15 A. Yes. 01:19</p> <p>16 Q. And is that an accurate quote?</p> <p>17 A. Yes.</p> <p>18 Q. Is it your understanding now that they</p> <p>19 did, in fact, have twelve months of data?</p> <p>20 A. Yes. 01:19</p> <p>21 Q. Why did you say that if you cannot have</p> <p>22 a level of trust in the investigators you might as</p> <p>23 well pack it in?</p> <p>24 A. Because it is impossible for us to go</p>	<p>51</p> <p>1 through Exhibit 24 now? 01:23</p> <p>2 A. Yes.</p> <p>3 Q. It's a chain of e-mails. Regarding the</p> <p>4 last e-mail, does it purport to summarize the</p> <p>5 meeting between you and Michael Friedman and Ken 01:24</p> <p>6 Verburg that we discussed earlier that occurred on</p> <p>7 August 21, 2001?</p> <p>8 A. Yes.</p> <p>9 Q. And you've read through it now; is that</p> <p>10 correct? 01:24</p> <p>11 A. Yes, I did.</p> <p>12 Q. Does it jog your memory at all about</p> <p>13 what happened at that meeting?</p> <p>14 A. Yes.</p> <p>15 Q. Is there anything that you read in this 01:24</p> <p>16 summary that seems inconsistent with your</p> <p>17 recollection of the meeting?</p> <p>18 A. The part about "suffice it to say, by</p> <p>19 the end of the meeting both editors expressed</p> <p>20 greater confidence in our motives and activities." 01:24</p> <p>21 Q. And you would say that's not accurate?</p> <p>22 A. I don't believe that's accurate at all.</p> <p>23 Of course, he is, this is what he believes. It is</p> <p>24 not what I believe.</p>
<p>50</p> <p>1 through all the records of any study we get. I 01:19</p> <p>2 can't possibly go into the laboratories and check</p> <p>3 the lab data. I can't possibly look at the</p> <p>4 medical records of every patient. That's just</p> <p>5 impossible for me to do. 01:19</p> <p>6 So I have to trust that the</p> <p>7 authors, the investigators, who send material to</p> <p>8 me, are telling the truth and providing the data</p> <p>9 to the best of their ability fully and completely.</p> <p>10 Q. And did the defendants do that with 01:20</p> <p>11 regard to the JAMA article?</p> <p>12 A. No.</p> <p>13 MR. HALPER: Object as to form.</p> <p>14 MR. MONTGOMERY: I'd like to ask the</p> <p>15 Court Reporter to mark what will be Exhibit 24. 01:20</p> <p>16 (WHEREUPON Deposition Exhibit</p> <p>17 No. 24 was marked as of</p> <p>18 1/12/2007.)</p> <p>19 BY MR. MONTGOMERY:</p> <p>20 Q. For the record, Exhibit 24 is an e-mail 01:20</p> <p>21 from Joy Dicker, D-I-C-K-E-R, to Mona Wahba dated</p> <p>22 August 23, 2001. (Document tendered to the</p> <p>23 witness.)</p> <p>24 Have you had a chance to read</p>	<p>52</p> <p>1 Q. So at the end of the meeting in your 01:25</p> <p>2 opinion you had no greater confidence in</p> <p>3 defendants' motives and activities?</p> <p>4 A. I had greater confidence that they</p> <p>5 understood what the expectation, what my 01:25</p> <p>6 expectation and the expectation of JAMA and I</p> <p>7 believe other similar peer-review journals expect,</p> <p>8 and that they said that they would make sure</p> <p>9 Dr. Silverstein would respond, not that they would</p> <p>10 write the letter. 01:25</p> <p>11 Q. When you say that Dr. Silverstein would</p> <p>12 respond, do you mean that his signature would be</p> <p>13 on the letter or that he would actually write the</p> <p>14 letter?</p> <p>15 A. I don't sign anything that I don't write 01:26</p> <p>16 or at least do the first draft or dictate or it's</p> <p>17 part of a meeting in which we exchange thoughts</p> <p>18 and I say in general this is what I need.</p> <p>19 For the most part, I write my own</p> <p>20 letters but occasionally it will be a group. But 01:26</p> <p>21 if I receive something and the signatories had no</p> <p>22 role in writing the draft and editing the draft, I</p> <p>23 don't think they should sign it.</p> <p>24 Q. When you were talking about the letter</p>

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<p>53</p> <p>1 that you expected to receive, do you mean the one 01:27</p> <p>2 that would be published in JAMA as a response to</p> <p>3 the other letters to the editor?</p> <p>4 A. Yes. That's one of the things we</p> <p>5 discussed. That's primarily what we discussed, as 01:27</p> <p>6 a matter of fact, because it was their explanation</p> <p>7 of why the information came in as such.</p> <p>8 Q. I'd like you to please look at the</p> <p>9 second page of Exhibit 24, Bates number ending</p> <p>10 631. Do you see Item No. 5 on that page? 01:27</p> <p>11 A. Yes.</p> <p>12 Q. I'm going to just read the first</p> <p>13 sentence into the record. It says "In order to</p> <p>14 counter the lack of credibility and cynicism of</p> <p>15 our critics, she suggested that we have the raw 01:27</p> <p>16 data set independently analyzed by a statistician</p> <p>17 unaffiliated with the study." Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. Did you make that suggestion?</p> <p>20 A. What I said to her was that one of the 01:28</p> <p>21 things, or to him, excuse me, that we were</p> <p>22 contemplating, we JAMA, having a requirement for</p> <p>23 clinical trials that we would not accept the</p> <p>24 statistical analysis if it had been performed only</p>	<p>55</p> <p>1 wherewithal to do the investigation and then tell 01:30</p> <p>2 me that the investigation proved that what I was</p> <p>3 given was accurate.</p> <p>4 Q. Was that a change in policy for JAMA?</p> <p>5 A. Yes. 01:31</p> <p>6 Q. When did that change in policy occur</p> <p>7 officially?</p> <p>8 A. We had discussed it for a while. I</p> <p>9 think it was, I don't know the exact date, but</p> <p>10 we've had it for maybe two or three years now. 01:31</p> <p>11 Q. So it was not in place at the time the</p> <p>12 JAMA article was published?</p> <p>13 A. No.</p> <p>14 Q. At the time you had the meeting with</p> <p>15 Dr. Verburg and Dr. Friedman, did you then apply 01:31</p> <p>16 that requirement to Pharmacia specifically before</p> <p>17 it was applying to everyone else?</p> <p>18 A. No. I didn't apply, this paper had</p> <p>19 already been published. As such, it was not</p> <p>20 withdrawn because what was in the data, I had no 01:31</p> <p>21 reason to believe that there was any question</p> <p>22 about the analysis of the data that were analyzed.</p> <p>23 And therefore, I couldn't pull this paper because</p> <p>24 it was false in what was presented. But I did</p>
<p>54</p> <p>1 by the sponsor, especially if it was a for-profit 01:28</p> <p>2 sponsor, that we would require that if we were</p> <p>3 going to accept a study it would only be after all</p> <p>4 the data were provided or whatever data thought</p> <p>5 necessary by a faculty statistician, that the data 01:29</p> <p>6 would be provided to him or her and that he or she</p> <p>7 would re-analyze in any way they thought and that</p> <p>8 they would then verify that the statistical</p> <p>9 analysis was accurate. And we have subsequently,</p> <p>10 we are the only journal that does that. We 01:29</p> <p>11 require a faculty member. And the reason we do</p> <p>12 that is because if anyone calls to question the</p> <p>13 voracity of anything in a paper and it requires</p> <p>14 more than I have the ability to do, I call the</p> <p>15 Dean and ask for an investigation. I have done 01:30</p> <p>16 that. And I want that to be something that I can</p> <p>17 do for the statistical analysis also.</p> <p>18 It is not because I think that the</p> <p>19 statisticians or the scientists who work for</p> <p>20 companies are any less smart, because they're very 01:30</p> <p>21 smart, or any less honest or any less clever. It</p> <p>22 is simply that I can go to a third party who has a</p> <p>23 stake in assuring the voracity of his or her</p> <p>24 faculty is assured, and that person has the</p>	<p>56</p> <p>1 require that the investigators respond to the 01:32</p> <p>2 statements made in the two letters to the editor,</p> <p>3 to put this in context.</p> <p>4 Q. Did you tell Dr. Verburg and</p> <p>5 Dr. Friedman that in order for further articles to 01:32</p> <p>6 be published about the CLASS study, that they</p> <p>7 would have to meet the independent analysis</p> <p>8 requirement that you just said?</p> <p>9 A. No.</p> <p>10 Q. Okay. Going back to this document, 01:32</p> <p>11 Exhibit 24, Item 5 on the second page says that</p> <p>12 you suggested an independent analysis. I forget</p> <p>13 at this point. Did you actually make that</p> <p>14 suggestion?</p> <p>15 A. I said in the future that's something we 01:33</p> <p>16 might do. So no one or at least there would be</p> <p>17 less likelihood that people would call to question</p> <p>18 the voracity of that aspect of your study.</p> <p>19 Q. Did you suggest that such an analysis be</p> <p>20 done of the CLASS data specifically? 01:33</p> <p>21 A. I don't recall I did that. I might</p> <p>22 have, but I don't recall.</p> <p>23 Q. Do you know whether or not any such</p> <p>24 analysis was performed?</p>



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<p>57</p> <p>1 A. No. 01:33</p> <p>2 MR. MONTGOMERY: I ask the Court</p> <p>3 Reporter to mark what will be Exhibit 25.</p> <p>4 (WHEREUPON Deposition Exhibit</p> <p>5 No. 25 was marked as of 01:34</p> <p>6 1/12/2007.)</p> <p>7 BY MR. MONTGOMERY:</p> <p>8 Q. For the record, Exhibit 25 is an e-mail</p> <p>9 from James Lefkowitz, L-E-F-K-O-W-I-T-H, to</p> <p>10 Michael Friedman and Kenneth Verburg dated 01:34</p> <p>11 August 20, 2001. (Document tendered to the</p> <p>12 witness.)</p> <p>13 Have you had a chance to read</p> <p>14 through Exhibit 25?</p> <p>15 A. Yes. 01:35</p> <p>16 Q. Have you ever seen this before?</p> <p>17 A. No. Have I seen those words or words</p> <p>18 similar to it?</p> <p>19 Q. On this document.</p> <p>20 A. Yes, but I've never seen this document. 01:35</p> <p>21 Q. So were representations essentially</p> <p>22 similar to what's memorialized in Exhibit 25 made</p> <p>23 to you at the meeting you had with Drs. Friedman</p> <p>24 and Verburg?</p>	<p>59</p> <p>1 Q. Okay. In the third paragraph of Exhibit 01:37</p> <p>2 25, there's a mention of informative censoring?</p> <p>3 A. Did I read this? Yes.</p> <p>4 Q. No, no. I'm pointing out the phrase</p> <p>5 "informative censoring." Are you familiar with 01:37</p> <p>6 that phrase?</p> <p>7 A. I generally know what it means. I don't</p> <p>8 know what it means in this particular message.</p> <p>9 Q. So do you have an understanding of</p> <p>10 whether informative censoring is relative to why 01:38</p> <p>11 defendants did not publish the full CLASS study</p> <p>12 data in the JAMA article?</p> <p>13 A. I have an understanding of how they</p> <p>14 might believe that informative censoring would be</p> <p>15 relative to what was published. 01:38</p> <p>16 Q. Relevant you mean?</p> <p>17 A. Why they might believe it was relative</p> <p>18 and relevant, not relative, relevant to, why they</p> <p>19 might believe it was relevant.</p> <p>20 Q. And what's that understanding? 01:38</p> <p>21 A. That sometimes you have to in your</p> <p>22 statistical analysis or the way you describe</p> <p>23 something, to make it easier for the reader to</p> <p>24 understand the true finding, that you don't go</p>
<p>58</p> <p>1 A. Excuse me. Is this related to, does 01:35</p> <p>2 this reflect what we discussed with them?</p> <p>3 Q. Yes.</p> <p>4 A. We didn't discuss this with them.</p> <p>5 What I discussed with Drs. Friedman 01:35</p> <p>6 and Verburg was just generally, they were</p> <p>7 discussing why they did six months and different</p> <p>8 kinds of words, and I said it's up to you, it's up</p> <p>9 to your authors, the scientists who did this</p> <p>10 study, the investigators, to explain why what they 01:36</p> <p>11 did meets the requirement in reply to the two</p> <p>12 letters which they had. They had the letters</p> <p>13 obviously. But we didn't discuss words or who was</p> <p>14 going to write what or anything.</p> <p>15 Q. Did you discuss the substance of what 01:36</p> <p>16 they intended to put in their letter?</p> <p>17 A. No, because this letter was to come from</p> <p>18 the investigators, not from them.</p> <p>19 Q. And did they agree to that, that the</p> <p>20 investigators -- 01:37</p> <p>21 A. We never discussed that per se. I said</p> <p>22 you better make sure that the investigators</p> <p>23 respond to the questions raised in the two</p> <p>24 letters.</p>	<p>60</p> <p>1 into extreme detail and instead you make it 01:39</p> <p>2 simpler. That's generally what it means.</p> <p>3 MR. MONTGOMERY: I'd like to ask the</p> <p>4 Court Reporter to mark what will be Exhibit 26.</p> <p>5 (WHEREUPON Deposition Exhibit 01:40</p> <p>6 No. 26 was marked as of</p> <p>7 1/12/2007.)</p> <p>8 BY MR. MONTGOMERY:</p> <p>9 Q. For the record, Exhibit 26 is an</p> <p>10 unsigned draft of a letter dated September 6, 01:40</p> <p>11 2001, to Dr. DeAngelis from Steven Geis.</p> <p>12 (Document tendered to the witness.)</p> <p>13 Just so you understand, this was</p> <p>14 produced to us by defendants, and neither</p> <p>15 defendants or JAMA produced a signed copy. So my 01:42</p> <p>16 first question is have you ever received a letter</p> <p>17 similar to this?</p> <p>18 A. I don't recall ever receiving this.</p> <p>19 Q. Would you please look at the second page</p> <p>20 of Exhibit 26, Bates ending 644. Towards the end 01:42</p> <p>21 of the paragraph at the top of that page I'll read</p> <p>22 into the record, it says "In this spirit, I would</p> <p>23 like to take this opportunity to suggest an</p> <p>24 independent review of the CLASS data take place to</p>

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<p>61</p> <p>1 address specifically whether the data presented 01:42</p> <p>2 and conclusions drawn in the JAMA manuscript are</p> <p>3 accurate and are comparable to the description of</p> <p>4 GI safety and overall safety obtained from the</p> <p>5 longer term follow-up results." Do you see that? 01:42</p> <p>6 A. Yes.</p> <p>7 Q. Do you have any understanding whether</p> <p>8 such an independent review ever took place?</p> <p>9 A. Not to my knowledge.</p> <p>10 MR. MONTGOMERY: I'd like to ask the 01:43</p> <p>11 Court Reporter to mark what will be Exhibit 27.</p> <p>12 (WHEREUPON Deposition Exhibit</p> <p>13 No. 27 was marked as of</p> <p>14 1/12/2007.)</p> <p>15 BY MR. MONTGOMERY: 01:43</p> <p>16 Q. Once again, this is a long document, so</p> <p>17 like I said, if you want to read the whole thing,</p> <p>18 that's fine. For the record, it's an e-mail with</p> <p>19 three attachments from Carolyn Wilson to George</p> <p>20 Geis and a number of other individuals dated 01:43</p> <p>21 March 20, 2000. (Document tendered to the</p> <p>22 witness.)</p> <p>23 I'm actually only going to ask you</p> <p>24 about the third attachment, which is the last two</p>	<p>63</p> <p>1 manuscript meeting. So it had to be before we got 01:46</p> <p>2 the manuscript.</p> <p>3 Q. I can refresh your memory actually. The</p> <p>4 really thick exhibit, Exhibit 21.</p> <p>5 A. Oh, May 2000. 01:46</p> <p>6 Q. Underneath it, the study dates.</p> <p>7 A. September '98 to 17 March 2000. So</p> <p>8 this --</p> <p>9 Q. So if that is correct, then the meeting</p> <p>10 memorialized in Exhibit 27, does it appear that 01:47</p> <p>11 that took place before the CLASS study was</p> <p>12 completed?</p> <p>13 A. Right.</p> <p>14 MR. HALPER: I'll object on foundation.</p> <p>15 BY MR. MONTGOMERY: 01:47</p> <p>16 Q. Looking at the second to last page of</p> <p>17 Exhibit 27, Bates number ending 816, do you see</p> <p>18 towards the bottom of the page there's a bullet</p> <p>19 that says "Trial Design Issues"?</p> <p>20 A. Yes. 01:47</p> <p>21 Q. And then underneath that the third</p> <p>22 bullet down says "Worse case. We have to attack</p> <p>23 the trial design if we do not see the results we</p> <p>24 want." Do you see that?</p>
<p>62</p> <p>1 pages of this document. I'm actually only going 01:44</p> <p>2 to ask you about that first page. You're free to</p> <p>3 read the rest if you want to.</p> <p>4 Does this appear to be notes of the</p> <p>5 meeting of the CLASS steering committee? 01:45</p> <p>6 A. That's what it looks like.</p> <p>7 Q. Do you see where it says Required</p> <p>8 Attendees towards the top?</p> <p>9 A. Yes.</p> <p>10 Q. Do you recognize any of those names? 01:45</p> <p>11 A. I'm trying to see if any of these</p> <p>12 authors were on. Offhand --</p> <p>13 Q. Maybe the simpler question is do you</p> <p>14 know any of the individuals listed?</p> <p>15 A. No. 01:46</p> <p>16 Q. What's the purported date of this</p> <p>17 meeting?</p> <p>18 A. February 21, 2000.</p> <p>19 Q. And if you recall, was that before the</p> <p>20 end of the CLASS study, before the study was 01:46</p> <p>21 completed?</p> <p>22 A. I don't know the exact date of</p> <p>23 completion. I know that this had to be before,</p> <p>24 certainly before we presented it at the first</p>	<p>64</p> <p>1 A. Yes. 01:47</p> <p>2 Q. Do you have an understanding of what</p> <p>3 "attack the trial design" means in that context?</p> <p>4 MR. HALPER: Objection, foundation.</p> <p>5 THE WITNESS: I don't know specifically 01:47</p> <p>6 what they mean. I know what they mean to me, but</p> <p>7 I may have an inaccurate understanding.</p> <p>8 BY MR. MONTGOMERY:</p> <p>9 Q. What is your understanding of that</p> <p>10 statement? 01:48</p> <p>11 A. We don't like what we find, we fix it.</p> <p>12 Q. How would they fix it?</p> <p>13 A. Manipulation, attacking data,</p> <p>14 manipulation.</p> <p>15 Q. And in your opinion is that what 01:48</p> <p>16 defendants ultimately did with regard to the CLASS</p> <p>17 data?</p> <p>18 MR. HALPER: Objection, foundation.</p> <p>19 THE WITNESS: I have no idea.</p> <p>20 BY MR. MONTGOMERY: 01:48</p> <p>21 Q. In your opinion is attacking the trial</p> <p>22 design if you don't get the results you want</p> <p>23 proper scientific conduct?</p> <p>24 A. No.</p>

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<p>65</p> <p>1 MR. MONTGOMERY: I'd like to ask the 01:48</p> <p>2 Court Reporter to mark what will be Exhibit 28.</p> <p>3 (WHEREUPON Deposition Exhibit</p> <p>4 No. 28 was marked as of</p> <p>5 1/12/2007.) 01:49</p> <p>6 BY MR. MONTGOMERY:</p> <p>7 Q. This is another rather lengthy document.</p> <p>8 I can direct you to the part that I'm going to ask</p> <p>9 you about, but then you can read as much as you</p> <p>10 want. It is the third page, Bates number ending 01:49</p> <p>11 477, and the third full paragraph in that starting</p> <p>12 "With a bit of data massage." (Document tendered</p> <p>13 to the witness.)</p> <p>14 For the record, Exhibit 28 is an</p> <p>15 e-mail chain beginning with an e-mail from James 01:49</p> <p>16 Lefkowitz to Emilio Arbe, A-R-B-E, dated</p> <p>17 September 28, 2000.</p> <p>18 A. I read the paragraph, yes.</p> <p>19 Q. Have you read enough to understand the</p> <p>20 context? 01:50</p> <p>21 A. I can understand the context, yes.</p> <p>22 Q. Okay. I'll represent to you, this is</p> <p>23 one of the things you just have to take my word</p> <p>24 for it, that Emilio Arbe was a medical director in</p>	<p>67</p> <p>1 MR. MONTGOMERY: You can do that. 01:51</p> <p>2 MR. HALPER: Yes, right.</p> <p>3 BY MR. MONTGOMERY:</p> <p>4 Q. I'd like you to look at the paragraph</p> <p>5 beginning "With a bit of data massage." I'm going 01:51</p> <p>6 to read it into the record, the first sentence in</p> <p>7 any event. "With a bit of data massage, what</p> <p>8 Steve Geis and his team have done is to focus on</p> <p>9 the six-month data, for no other reason that it</p> <p>10 happens to look better, and this time they 01:51</p> <p>11 concentrate on the nonaspirin-treated patients,</p> <p>12 and ignore the fact that at no time interval did</p> <p>13 we see a statistically significant difference with</p> <p>14 diclofenac, whether one looks at patients taking</p> <p>15 aspirin or not, at six or at twelve months." 01:52</p> <p>16 Did defendants disclose any of this</p> <p>17 information to you prior to the publication of the</p> <p>18 JAMA article?</p> <p>19 MR. HALPER: Objection to form.</p> <p>20 THE WITNESS: No. 01:52</p> <p>21 BY MR. MONTGOMERY:</p> <p>22 Q. Did defendants ever disclose this</p> <p>23 information to you after the publication of the</p> <p>24 JAMA article?</p>
<p>66</p> <p>1 the -- 01:50</p> <p>2 MR. HALPER: No, no, you can't --</p> <p>3 MR. MONTGOMERY: I can.</p> <p>4 MR. HALPER: No, you can't, unless you</p> <p>5 want to switch seats and testify. 01:50</p> <p>6 MR. MONTGOMERY: I'm going to represent</p> <p>7 to her whatever I want to represent to her.</p> <p>8 MR. HALPER: Well, I don't think there's</p> <p>9 any basis to do it. I think it's an improper</p> <p>10 question. 01:50</p> <p>11 MR. MONTGOMERY: I haven't asked her a</p> <p>12 question -- all right. Your objection is noted.</p> <p>13 BY MR. MONTGOMERY:</p> <p>14 Q. I'm going to represent to you that he</p> <p>15 was a medical director at Pfizer at this time. 01:51</p> <p>16 MR. HALPER: I'm going to object to that</p> <p>17 representation. It's also not correct.</p> <p>18 MR. MONTGOMERY: At Pharmacia?</p> <p>19 MR. HALPER: Well, you don't seem to</p> <p>20 care about whether you're correct or not. 01:51</p> <p>21 MR. MONTGOMERY: He was a medical</p> <p>22 director at one of the defendant companies.</p> <p>23 MR. HALPER: Do you also want to tell</p> <p>24 her that he had nothing to do with the study?</p>	<p>68</p> <p>1 A. No. 01:52</p> <p>2 MR. HALPER: Objection to form.</p> <p>3 BY MR. MONTGOMERY:</p> <p>4 Q. In your opinion --</p> <p>5 MR. NELSON: When he asks the question, 01:52</p> <p>6 wait a second so he can object.</p> <p>7 THE WITNESS: Excuse me.</p> <p>8 BY MR. MONTGOMERY:</p> <p>9 Q. In your opinion is the conduct described</p> <p>10 in the language I just read to you proper 01:52</p> <p>11 scientific behavior?</p> <p>12 MR. HALPER: Objection, no foundation,</p> <p>13 assumes facts not in evidence, and to form.</p> <p>14 THE WITNESS: No.</p> <p>15 MR. MONTGOMERY: I'd like to ask the 01:52</p> <p>16 Court Reporter to mark what will be Exhibit 29.</p> <p>17 (WHEREUPON Deposition Exhibit</p> <p>18 No. 29 was marked as of</p> <p>19 1/12/2007.)</p> <p>20 BY MR. MONTGOMERY: 01:53</p> <p>21 Q. Once again, you can read the whole</p> <p>22 thing. I'm just going to ask you about your quote</p> <p>23 at the bottom of the first paragraph. (Document</p> <p>24 tendered to the witness.)</p>

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<p>69</p> <p>1 For the record, this is a copy of a 01:53  2 U.S. News &amp; World Report article dated  3 September 17, 2001, entitled "Physicians are  4 putting a stop to the publication of misleading  5 drug data." 01:53  6 Have you seen this article before?  7 A. Yes.  8 Q. Did you read it when it came out?  9 A. Yes.  10 Q. I'd like to direct you to your quote at 01:53  11 the bottom of the first paragraph of Exhibit 29.  12 It says "The company had twelve months of data and  13 didn't tell me. They know how upset I am." Do  14 you see that?  15 A. Yes. 01:54  16 Q. Is that an accurate quote?  17 A. Yes.  18 Q. Do you still believe that the company  19 had twelve months of data and did not tell you?  20 A. Yes. 01:54  21 MR. MONTGOMERY: I'd like to ask the  22 Court Reporter to mark what will be Exhibit 30.  23  24</p>	<p>71</p> <p>1 nice but it speaks okay I guess. 01:58  2 Q. Is there anything in the quotes that you  3 read from this transcript that you now disagree  4 with?  5 A. No. 01:58  6 MR. MONTGOMERY: I'd like to ask the  7 Court Reporter to mark what will be Exhibit 31.  8 (WHEREUPON Deposition Exhibit  9 No. 31 was marked as of  10 1/12/2007.) 01:59  11 BY MR. MONTGOMERY:  12 Q. I'm only going to be asking you about  13 the third paragraph of Dr. Silverstein, Simon, and  14 Faich's letter. (Document tendered to the  15 witness.) 01:59  16 A. One second.  17 Q. For the record, Exhibit 31 is a number  18 of letters to the editor from the November 21,  19 2001 issue of JAMA?  20 A. I'm missing a page. 02:00  21 MR. HALPER: Me too.  22 BY MR. MONTGOMERY:  23 Q. Are you? Which page?  24 A. 2399.</p>
<p>70</p> <p>1 (WHEREUPON Deposition Exhibit 01:54  2 No. 30 was marked as of  3 1/12/2007.)  4 BY MR. MONTGOMERY:  5 Q. Once again, a long document. I'm only 01:54  6 going to ask you what you were quoted as saying on  7 the third page, Bates number ending 617.  8 (Document tendered to the witness.)  9 For the record, Exhibit 30 is an  10 e-mail chain starting with an e-mail from Mary 01:55  11 Frances Faraji, F-A-R-A-J-I, to George Geis dated  12 January 20, 2002, and includes what appears to be  13 a transcript of an interview from WAMU-FM radio.  14 Do you recall being interviewed by  15 WAMU radio on or around January of 2002? 01:58  16 A. Yes.  17 Q. There's a lengthy quote from you on the  18 third and fourth page of Exhibit 30, Bates numbers  19 ending 716 and 618. Have you had a chance to read  20 through those quotes? 01:58  21 A. Yes.  22 Q. Are they accurate?  23 A. Pretty much, as near as I can remember.  24 It's radio, it's verbal. It doesn't read very</p>	<p>72</p> <p>1 MR. NELSON: The ones you're talking 02:00  2 about.  3 THE WITNESS: Of JAMA it would be, well,  4 it's 1957 and then it goes to 1959 and what I was  5 looking for is not here. 02:00  6 MR. HALPER: We can --  7 MR. MONTGOMERY: Can we go off the  8 record?  9 THE VIDEOGRAPHER: We are off the  10 record. The time now is approximately 2:00 p.m. 02:00  11 (WHEREUPON a recess was taken.)  12 THE VIDEOGRAPHER: We are back on the  13 record. The time now is approximately 2:01 p.m.  14 MR. MONTGOMERY: Are we now looking at  15 page Bates number ending 958 of Exhibit 31? 02:01  16 MR. NELSON: This doesn't have Bates  17 numbers.  18 THE WITNESS: This doesn't have page  19 numbers.  20 BY MR. MONTGOMERY: 02:01  21 Q. Okay, the second page of Exhibit 31.  22 Does this page contain a letter to JAMA from three  23 of the authors of The CLASS, the JAMA article?  24 A. Yes.</p>

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<p>73</p> <p>1 Q. I'd like to direct you to the top of the 02:02  2 second column, the sentence starting "Fourth."  3 "Fourth and most important, after the blind was  4 broken it became clear that there was a  5 differential dropout rate of NSAID patients with 02:02  6 GI intolerance or symptomatic ulcers, suggesting  7 that those patients at greatest risk were no  8 longer in the study. This type of informative  9 censoring leads to a bias, which potentially  10 invalidates statistical analysis of complicated 02:02  11 ulcers by the log rank test." Do you see that?  12 A. Yes.  13 Q. Do you have a general understanding of  14 what that point is?  15 A. Yes. 02:02  16 Q. Can you explain it to me in laymen's  17 terms?  18 A. It's a statistical argument that because  19 the people who benefit drop out sooner, that those  20 who remain in longer are the ones that don't have 02:03  21 as great a benefit.  22 That's as simple as I can put it  23 without giving you a course in bio-sadistics as  24 it's called.</p>	<p>75</p> <p>1 majority of our readers are not bio-statisticians 02:06  2 and could not necessarily understand that such  3 analyses may be acceptable statistically to some  4 if you understand. It's not what you would depend  5 that the average physician or clinician would 02:06  6 understand that these data are what they seem to  7 be.  8 The bottom line is as a physician,  9 I'm not a bio-statistician but I'm a fairly  10 sophisticated physician when it comes to being a 02:07  11 clinical researcher, I would never change my  12 practice or adopt something based on this kind of  13 analysis. And I seriously doubt that we ever  14 would have published it knowing this.  15 Q. Knowing that defendants were relying on 02:07  16 the informative censoring theory?  17 A. Exactly. But they explained it here.  18 Q. You can put this aside for now, but  19 we're going to come back to it so you'll want to  20 be able to reach it. 02:07  21 MR. MONTGOMERY: I'd like to ask the  22 Court Reporter to mark what will be Exhibit 32.  23  24</p>
<p>74</p> <p>1 Q. Please don't. 02:03  2 For the purposes of this  3 deposition, can we just refer to that as  4 defendants' informative censoring theory?  5 A. Yes, yes. 02:03  6 Q. Okay. Even if the informative censoring  7 theory were correct, in your mind would that  8 justify publishing only six months of data in the  9 JAMA article?  10 A. Had they informed us that that was what 02:04  11 they were doing, we would have to decide whether  12 we wanted to publish it or not because it's a  13 different way of analyzing data. And without  14 seeing what the data look like in the various  15 phases of doing this, it's extremely difficult to 02:04  16 see what they did. I can tell you that in general  17 in a clinical trial this is not an acceptable form  18 of statistical analysis for JAMA.  19 Q. And why is that?  20 A. Because I think it portrays a finding 02:05  21 that is not clinically accurate. And since JAMA,  22 the role of JAMA is to provide information to  23 clinicians and to other medical researchers but to  24 make patient care better. And because the vast</p>	<p>76</p> <p>1 (WHEREUPON Deposition Exhibit 02:08  2 No. 32 was marked as of  3 1/12/2007.)  4 BY MR. MONTGOMERY:  5 Q. I'm only going to ask you about the 02:08  6 second page of Exhibit 32, but feel free to read  7 as much of it as you feel is necessary. (Document  8 tendered to the witness.)  9 A. The entire page you want me to read?  10 Q. Really the first column. 02:08  11 Okay. Looking at the second page  12 of Exhibit 32, I'd like you to look at the last  13 full paragraph in the first column that starts  14 "Publishing." "Publishing and distributing  15 overoptimistic short-term data using post hoc 02:11  16 changes to the protocol, while omitting  17 disappointing long-term data of two trials, which  18 involved large numbers of volunteers, is  19 misleading." Do you see that?  20 A. Yes. 02:11  21 Q. Do you agree with that assessment?  22 A. Yes.  23 Q. Do you understand what "post hoc changes  24 to the protocol" means here?</p>

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<p>77</p> <p>1 A. It means after the fact. 02:11</p> <p>2 Q. Do you agree that this is an accurate</p> <p>3 description of what defendants did in this case</p> <p>4 with regard to the JAMA article?</p> <p>5 MR. HALPER: Objection to form. 02:11</p> <p>6 THE WITNESS: Yes.</p> <p>7 BY MR. MONTGOMERY:</p> <p>8 Q. Okay. Now, I'd like you to look at the</p> <p>9 first full paragraph in that column that starts</p> <p>10 "Two issues." 02:11</p> <p>11 A. Yes.</p> <p>12 Q. The third sentence begins "They argued,"</p> <p>13 and it's talking about the authors. I'll read it</p> <p>14 into the record. It says "They argued that a</p> <p>15 large and differential dropout rate had occurred 02:12</p> <p>16 during the later stage of the trial, which</p> <p>17 depleted patients with gastrointestinal adverse</p> <p>18 events preferentially in the groups taking</p> <p>19 nonsteroidal anti-inflammatory drugs and that</p> <p>20 these patients were at higher risk of developing 02:12</p> <p>21 ulcer related complications." Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. Is that a restatement of the informative</p> <p>24 censoring theory we discussed earlier?</p>	<p>79</p> <p>1 authors. 02:13</p> <p>2 Q. What actually happened?</p> <p>3 A. Well, if you go to the FDA data, this is</p> <p>4 what they're talking about right here, it says the</p> <p>5 absolute number of dropouts and withdrawals, both 02:13</p> <p>6 overall and due to GI adverse events, increased</p> <p>7 gradually without any sudden increase after six</p> <p>8 months and withdrawal rates stayed roughly</p> <p>9 constant in different treatment groups during the</p> <p>10 entire follow-up period, meaning you would have 02:14</p> <p>11 expected to see a big change, and that's not what</p> <p>12 happened.</p> <p>13 Q. All right. I'd like you to look at the</p> <p>14 next sentence "In addition, there was no robust</p> <p>15 evidence that gastrointestinal adverse events were 02:14</p> <p>16 actually a risk factor for ulcer related</p> <p>17 complications." Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. In your opinion is that relevant to the</p> <p>20 informative censoring theory? 02:14</p> <p>21 A. It could be.</p> <p>22 Q. And why is that?</p> <p>23 A. By virtue of what it says. If you don't</p> <p>24 have robust evidence for something, I mean your</p>
<p>78</p> <p>1 A. Essentially, yes. 02:12</p> <p>2 Q. The next sentence says "However, the</p> <p>3 absolute number of dropouts and withdrawals, both</p> <p>4 overall and due to gastrointestinal adverse</p> <p>5 events, increased gradually, without any sudden 02:12</p> <p>6 increase after six months, and withdrawal rates</p> <p>7 stayed roughly constant in different treatment</p> <p>8 groups during the entire follow-up period." Do</p> <p>9 you see that?</p> <p>10 A. Yes. 02:12</p> <p>11 Q. Is that relevant to you in the</p> <p>12 informative censoring theory in your opinion?</p> <p>13 A. Yes.</p> <p>14 Q. And why is that?</p> <p>15 A. Because you would expect to see a 02:13</p> <p>16 substantial decrease, and it usually would occur</p> <p>17 in a more rapid dropoff.</p> <p>18 Q. At what point?</p> <p>19 A. Well, it depends where you are on the,</p> <p>20 it wouldn't be where the cutoff was made by where 02:13</p> <p>21 you would analyze.</p> <p>22 What actually happened was not</p> <p>23 exactly what was described or what you would</p> <p>24 assume happened reading the explanation by the</p>	<p>80</p> <p>1 robust may not be my robust. 02:14</p> <p>2 MR. MONTGOMERY: Let's go off the</p> <p>3 record.</p> <p>4 THE VIDEOGRAPHER: We are off the</p> <p>5 record. The time now is 2:14. This will conclude 02:15</p> <p>6 Videotape No. 3.</p> <p>7 (WHEREUPON a recess was taken.)</p> <p>8 THE VIDEOGRAPHER: This will begin</p> <p>9 Videotape No. 3 of the videotaped deposition of</p> <p>10 the Catherine DeAngelis taken on the 12th day of 02:21</p> <p>11 January 2007, Case No. 03-1519. The time now is</p> <p>12 approximately 2:21 p.m., and I'll remind the</p> <p>13 witness she remains under oath.</p> <p>14 BY MR. MONTGOMERY:</p> <p>15 Q. Looking back at the second page of 02:21</p> <p>16 Exhibit 32. In light of what we talked about</p> <p>17 previously concerning informative censoring, in</p> <p>18 your opinion is defendants' theory of informative</p> <p>19 censoring valid?</p> <p>20 MR. HALPER: Objection, foundation, and 02:22</p> <p>21 to form.</p> <p>22 THE WITNESS: Is there, I missed the</p> <p>23 word, is their what of --</p> <p>24</p>

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<p>81</p> <p>1 BY MR. MONTGOMERY: 02:22</p> <p>2 Q. The theory of informative censoring.</p> <p>3 A. Is their theory?</p> <p>4 Q. Yes.</p> <p>5 MR. HALPER: I would also object that 02:22</p> <p>6 Dr. DeAngelis is here as a fact witness, not an</p> <p>7 expert witness, and the question goes to expert</p> <p>8 testimony.</p> <p>9 BY MR. MONTGOMERY:</p> <p>10 Q. You can answer to the extent you are 02:22</p> <p>11 able to.</p> <p>12 A. Well, as a matter of fact, what I was</p> <p>13 going to say was my understanding, and I am not an</p> <p>14 expert in statistical analysis, but in my</p> <p>15 understanding it's an interesting way of applying 02:22</p> <p>16 it. Whether it's valid I can't say. But had I</p> <p>17 been informed of all this, it may very well have</p> <p>18 changed the decision whether or not to publish in</p> <p>19 JAMA.</p> <p>20 Q. All right. Let's keep this one handy 02:23</p> <p>21 too. We'll be back to it, but we're done with it</p> <p>22 for now.</p> <p>23 MR. MONTGOMERY: I'd like to ask the</p> <p>24 Court Reporter to mark what will be Exhibit 33.</p>	<p>83</p> <p>1 get published, I'll say JAMA because I could speak 02:25</p> <p>2 about my own journal, or a journal like JAMA, that</p> <p>3 we go to great pangs to assure that what we</p> <p>4 published is trustworthy. And, therefore, if they</p> <p>5 get it from JAMA, they know it's a very good study 02:25</p> <p>6 that can be trusted because we place our integrity</p> <p>7 behind them.</p> <p>8 Q. Do pharmaceutical companies have detail</p> <p>9 persons distribute reprints of some articles from</p> <p>10 JAMA and other journals? 02:25</p> <p>11 MR. HALPER: Objection, no foundation,</p> <p>12 and I believe it also goes to expert testimony.</p> <p>13 THE WITNESS: Well, that I disagree</p> <p>14 because I was in practice for a long time before I</p> <p>15 came here. 02:26</p> <p>16 I know that various pharmaceutical</p> <p>17 and, well, pharmaceutical companies purchase</p> <p>18 reprints from JAMA. I also do know and have been</p> <p>19 handed, when I was at Hopkins in practice, handed</p> <p>20 reprints from various journals by pharmaceutical 02:26</p> <p>21 detail people.</p> <p>22 BY MR. MONTGOMERY:</p> <p>23 Q. And in your opinion does that sometimes</p> <p>24 allow doctors to see articles that they otherwise</p>
<p>82</p> <p>1 (WHEREUPON Deposition Exhibit 02:23</p> <p>2 No. 33 was marked as of</p> <p>3 1/12/2007.)</p> <p>4 BY MR. MONTGOMERY:</p> <p>5 Q. I'm just going to ask you about your 02:23</p> <p>6 very first quote on the first page. For the</p> <p>7 record, Exhibit 33 is a July 14, 2005 transcript</p> <p>8 from National Public Radio. (Document tendered to</p> <p>9 the witness.)</p> <p>10 I'd like to read a quote into the 02:24</p> <p>11 record. It's your first quote on the first page.</p> <p>12 It says "If a detail person working for a</p> <p>13 pharmaceutical company can hand a reprint of a</p> <p>14 publication from a high-powered journal like JAMA</p> <p>15 or NEJM to a doctor, that has a very significant 02:24</p> <p>16 effect on the physician."</p> <p>17 Is that an accurate quote? Did you</p> <p>18 say that?</p> <p>19 A. Yes.</p> <p>20 Q. Do you still agree with it? 02:24</p> <p>21 A. Yes.</p> <p>22 Q. Why do you agree that has a very</p> <p>23 significant effect on physicians?</p> <p>24 A. Because they know how difficult it is to</p>	<p>84</p> <p>1 wouldn't have had access to? 02:26</p> <p>2 A. Yes.</p> <p>3 Q. Would you turn back to Exhibit 32,</p> <p>4 please. Looking at the second page at the bottom,</p> <p>5 there's a sentence that says "Consequently." Do 02:27</p> <p>6 you see that sentence in the middle of the last</p> <p>7 paragraph?</p> <p>8 A. Yes, yes.</p> <p>9 Q. I'll read it into the record.</p> <p>10 "Consequently, CLASS may still be relied on by 02:27</p> <p>11 many physicians without reference to these flaws."</p> <p>12 Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Do you understand flaws to mean the</p> <p>15 criticisms that are described earlier in the 02:27</p> <p>16 paper?</p> <p>17 A. That's what he means I assume.</p> <p>18 Q. Do you agree that at the time this</p> <p>19 article was published in the British Medical</p> <p>20 Journal that that observation was true? 02:28</p> <p>21 MR. HALPER: Objection to form.</p> <p>22 THE WITNESS: I have no idea.</p> <p>23 MR. NELSON: I understand it's okay</p> <p>24 here, but please let him voice his objection.</p>



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<p>85</p> <p>1 MR. MONTGOMERY: I'd like to have the 02:28</p> <p>2 Court Reporter mark what will be Exhibit 34.</p> <p>3 (WHEREUPON Deposition Exhibit</p> <p>4 No. 34 was marked as of</p> <p>5 1/12/2007.) 02:28</p> <p>6 BY MR. MONTGOMERY:</p> <p>7 Q. I'm only going to be asking you about</p> <p>8 the third page. For the record, Exhibit 34 is a</p> <p>9 transcript of a National Public Radio broadcast</p> <p>10 dated December 16, 2005. (Document tendered to 02:29</p> <p>11 the witness.)</p> <p>12 I'd like to direct you to the</p> <p>13 middle of the third page of Exhibit 34, the middle</p> <p>14 of the third page. In the middle there's a quote</p> <p>15 where you say "They deliberately lied." Do you 02:31</p> <p>16 see that?</p> <p>17 A. Yes.</p> <p>18 Q. Is that an accurate quote?</p> <p>19 A. If it's here, I said it.</p> <p>20 Q. Do you have any reason to believe you 02:31</p> <p>21 didn't say it?</p> <p>22 A. Oh, I very likely did say it. In fact,</p> <p>23 if it's here I believe it, yes, I said it.</p> <p>24 Q. And who are you referring to in "they"?</p>	<p>87</p> <p>1 months. 02:33</p> <p>2 Q. In the same sense, do you consider the</p> <p>3 JAMA article that was printed to be a lie?</p> <p>4 A. No. The study as it exists with six</p> <p>5 month data arguably is accurate. If it was a lie 02:33</p> <p>6 and I could prove that what was in here is wrong,</p> <p>7 I would have pulled the paper.</p> <p>8 What is in here is, you notice that</p> <p>9 the editorial that accompanied this, which is very</p> <p>10 important, but if you have the editorial it's very 02:34</p> <p>11 clear in that editorial this is exciting,</p> <p>12 preliminary news, stay tuned, essentially, he</p> <p>13 didn't say that, but it said we have to follow and</p> <p>14 see what happens over time.</p> <p>15 So these data while the analysis I 02:34</p> <p>16 think paints a picture that is arguably painted in</p> <p>17 a positive way, the analysis of the data the way</p> <p>18 it was done, as far as I can tell, can be argued</p> <p>19 as legitimate. Is it cherry-picking? I don't see</p> <p>20 the raw data, I have never seen the raw data. So 02:35</p> <p>21 I don't know what they meant by cherry-picking.</p> <p>22 If it meant that they only took the patients they</p> <p>23 wanted to or they only analyzed the patients they</p> <p>24 wanted to, then this picture is absolutely false.</p>
<p>86</p> <p>1 A. The authors. 02:31</p> <p>2 Q. The authors of the JAMA article?</p> <p>3 A. Yes.</p> <p>4 Q. And how did you mean they lied?</p> <p>5 A. Forgive me, but I have to give you an 02:31</p> <p>6 example. I'm Catholic, okay, and I was taught</p> <p>7 that when you admit to stealing something and you</p> <p>8 say I stole a rope, make sure you also say there</p> <p>9 was a horse behind the rope.</p> <p>10 So lying is if you only say I stole 02:32</p> <p>11 a rope and you neglect to say that there was a</p> <p>12 horse behind the rope, and in that sense they lied</p> <p>13 because when we directly asked them, the way we</p> <p>14 ask the question, the way the question was asked</p> <p>15 to the author, do you have more than six months 02:32</p> <p>16 data or do you have more data, because they said</p> <p>17 the study was complete at six months, they said to</p> <p>18 us, the way they wrote it to us, we said our</p> <p>19 understanding is that this study is over, it's six</p> <p>20 months, is that true, and they said yes, you are 02:33</p> <p>21 right, the study was finished after six months.</p> <p>22 When we asked about patient information</p> <p>23 thereafter, they said patients could be followed</p> <p>24 further if they wanted to but the study is for six</p>	<p>88</p> <p>1 If the statistical analysis 02:35</p> <p>2 performed the way it was is accurate, then it</p> <p>3 means for six months what is projected in this</p> <p>4 paper is accurate.</p> <p>5 However, looking at it twelve 02:36</p> <p>6 months out, and this study was designed to look at</p> <p>7 not months it was designed to look at I believe it</p> <p>8 was forty incidences, it took a little over a</p> <p>9 year, sixteen months I believe, to get to I think</p> <p>10 they got finally to forty-four gastrointestinal 02:36</p> <p>11 bleeding references. That was the endpoint. And</p> <p>12 at that endpoint there was no difference. But at</p> <p>13 six months they had not reached that endpoint.</p> <p>14 And to have said this is a six-month study was an</p> <p>15 interesting way to look at the data because that's 02:36</p> <p>16 not, it was not designed as a six-month study, it</p> <p>17 was designed as a study to look at forty</p> <p>18 incidences and it took more than a year, twelve</p> <p>19 months, to reach that point.</p> <p>20 So extrapolating, they couldn't say 02:37</p> <p>21 that it was a twelve month, they didn't know how</p> <p>22 long it would take to reach forty. It's possible</p> <p>23 they could have reached forty incidences in six</p> <p>24 months, but they didn't, it took them a year. And</p>

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<p>89</p> <p>1 at that point there was no difference between this 02:37</p> <p>2 drug and the others.</p> <p>3 Q. Would you agree that the JAMA article</p> <p>4 was misleading --</p> <p>5 A. Yes. 02:37</p> <p>6 Q. -- for failing -- let me finish, please.</p> <p>7 Would you agree that the JAMA</p> <p>8 article was misleading for failing to acknowledge</p> <p>9 the existence of post six-month data?</p> <p>10 A. Yes. 02:37</p> <p>11 Q. Okay. Going back to the third page of</p> <p>12 Exhibit 34, there's another quote further down the</p> <p>13 page by you. It says "When they went out to</p> <p>14 twelve months, it turned out there was no</p> <p>15 difference. And then we got into trouble and we 02:37</p> <p>16 made them write a letter describing what they had</p> <p>17 done and admitting that they had lied to us."</p> <p>18 Is that an accurate quote, as far</p> <p>19 as you can tell?</p> <p>20 A. Yeah. 02:38</p> <p>21 Q. Do you still agree with it?</p> <p>22 A. Yes. Only I don't think we were the</p> <p>23 only ones. We got in trouble because we were in</p> <p>24 trouble with ourselves because integrity means a</p>	<p>91</p> <p>1 you're quoted as saying "The authors actually lied 02:42</p> <p>2 to us." Is that correct?</p> <p>3 A. Yeah. Is this supposedly something I</p> <p>4 said to them?</p> <p>5 Q. According to, let me read it again, yes. 02:42</p> <p>6 It says "The authors actually lied to us, said</p> <p>7 Dr. Catherine DeAngelis, the publication's editor</p> <p>8 in chief."</p> <p>9 A. That's a quote taken from -- when is</p> <p>10 this? June of this year? JAMA wasn't happy. 02:42</p> <p>11 That's a paraphrase of JAMA's editor isn't happy.</p> <p>12 The authors actually lied to us --</p> <p>13 Q. The quote in the previous document was</p> <p>14 "they deliberately lied."</p> <p>15 A. So all I can say is I do not recall 02:43</p> <p>16 talking to these people. It looks like what we</p> <p>17 say in editing a paraphrase of a previous</p> <p>18 publication. I'm not saying that I didn't talk to</p> <p>19 them because I speak to lots of people every day.</p> <p>20 But Investor's Business Daily is not, I don't talk 02:43</p> <p>21 to people usually in this kind of thing. But it's</p> <p>22 pretty close to what I said to somebody else.</p> <p>23 Q. Would you agree that the authors of the</p> <p>24 JAMA article did lie to you?</p>
<p>90</p> <p>1 lot to us, and people trust us. 02:38</p> <p>2 MR. HALPER: Can I talk to you off the</p> <p>3 record for a second?</p> <p>4 MR. MONTGOMERY: Sure. Let's go off the</p> <p>5 record. 02:38</p> <p>6 THE VIDEOGRAPHER: Okay. We are going</p> <p>7 off the record. The time now is approximately</p> <p>8 2:37.</p> <p>9 (WHEREUPON a recess was taken.)</p> <p>10 THE VIDEOGRAPHER: Okay. We are back on 02:41</p> <p>11 the record. The time now is approximately</p> <p>12 2:41 p.m.</p> <p>13 MR. MONTGOMERY: I'd like to ask the</p> <p>14 Court Reporter to mark what will be Exhibit 35.</p> <p>15 (WHEREUPON Deposition Exhibit 02:42</p> <p>16 No. 35 was marked as of</p> <p>17 1/12/2007.)</p> <p>18 BY MR. MONTGOMERY:</p> <p>19 Q. For the record, this is an article from</p> <p>20 the Investor's Business Daily dated June 19, 2006. 02:42</p> <p>21 (Document tendered to the witness.)</p> <p>22 I'm just going to ask you about</p> <p>23 your quote at the bottom of the page, but read as</p> <p>24 much as you need. At the bottom of the page</p>	<p>92</p> <p>1 A. Yes. 02:44</p> <p>2 Q. Okay. We'll move on.</p> <p>3 MR. MONTGOMERY: I'd like to ask the</p> <p>4 Court Reporter to mark what will be Exhibit 36.</p> <p>5 (WHEREUPON Deposition Exhibit 02:44</p> <p>6 No. 36 was marked as of</p> <p>7 1/12/2007.)</p> <p>8 BY MR. MONTGOMERY:</p> <p>9 Q. Do you recognize Exhibit 36? (Document</p> <p>10 tendered to the witness.) 02:44</p> <p>11 A. Yes.</p> <p>12 Q. What is it?</p> <p>13 A. This is not the current one but it's</p> <p>14 close. This is dated 8/30/2001 so, okay.</p> <p>15 Q. And what is this? 02:45</p> <p>16 A. This is our authorship form, must be</p> <p>17 signed, everything on here, all the requirements,</p> <p>18 must be signed or we won't publish an article.</p> <p>19 Every author must sign and must indicate that he</p> <p>20 or she has done enough to be a qualified author. 02:45</p> <p>21 Q. So is it your understanding that every</p> <p>22 author of the JAMA article signed and submitted</p> <p>23 one of these forms?</p> <p>24 A. They had to.</p>

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<p>93</p> <p>1 Q. Does JAMA still maintain these forms? 02:45</p> <p>2 A. We don't have these forms from 2000, no.</p> <p>3 Q. How long do you keep them?</p> <p>4 A. It depends what kind of document it is.</p> <p>5 Q. All right. I'd like you to look down at 02:46</p> <p>6 Section D on the first page. It says "To qualify</p> <p>7 for authorship, you must check at least one box</p> <p>8 for each of the three categories of contributions</p> <p>9 listed below"; is that correct?</p> <p>10 A. That's correct. 02:46</p> <p>11 Q. So does that mean that in order to</p> <p>12 qualify as an author for JAMA, an author or a</p> <p>13 potential author would have to be able to check</p> <p>14 one box in Category 1, one box in Category 2, and</p> <p>15 one box in Category 3 of Section D? 02:46</p> <p>16 A. Yes.</p> <p>17 Q. What's the purpose of these</p> <p>18 requirements?</p> <p>19 A. It's for us to be sure that each name,</p> <p>20 the name of each person on there, is legitimate to 02:46</p> <p>21 qualify as an author for JAMA. They must either</p> <p>22 participated and take responsibility for either at</p> <p>23 least part of the content, that they have to</p> <p>24 either been involved in the conception or design,</p>	<p>95</p> <p>1 (WHEREUPON Deposition Exhibit 02:48</p> <p>2 No. 37 was marked as of</p> <p>3 1/12/2007.)</p> <p>4 BY MR. MONTGOMERY:</p> <p>5 Q. For the record, Exhibit 37 is an e-mail 02:48</p> <p>6 from Mona Wahba to Leland Loose dated February 16,</p> <p>7 2000. (Document tendered to the witness.)</p> <p>8 I'm only going to be asking you</p> <p>9 about the second full paragraph on the page, but</p> <p>10 read as much as you need to. 02:48</p> <p>11 A. "Not for a while yet," that one you</p> <p>12 mean?</p> <p>13 Q. Yes. I'd like to direct you to the</p> <p>14 sentence, you can probably guess which one, the</p> <p>15 second to the last, "Believe it or not, a draft 02:49</p> <p>16 manuscript has already been written with a sort of</p> <p>17 fill in the blanks depending on what actually</p> <p>18 happens." Do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. In your experience is that a typical 02:49</p> <p>21 scientific practice?</p> <p>22 A. It depends what aspect. If it's the</p> <p>23 first part, the introduction, pretty common</p> <p>24 because you're just setting the background. If</p>
<p>94</p> <p>1 the acquisition of the data or the analysis and 02:47</p> <p>2 interpretation of it, and that they were involved</p> <p>3 in either the drafting of the manuscript or</p> <p>4 critical revision of the manuscript for important</p> <p>5 intellectual content, and they have to say if they 02:47</p> <p>6 were involved in any of the others.</p> <p>7 They don't need to check one of</p> <p>8 these, they could say no additional contributions,</p> <p>9 but for us we want to know who said they had the</p> <p>10 statistical expertise, who obtained the funding, 02:47</p> <p>11 all that kind of stuff.</p> <p>12 Q. As the editor in chief of JAMA, do you</p> <p>13 think you're familiar with the expectations of</p> <p>14 JAMA's readership?</p> <p>15 A. Yes. 02:47</p> <p>16 Q. At the time the JAMA article was</p> <p>17 published, do you think that JAMA's readership had</p> <p>18 expectations regarding the requirements of</p> <p>19 authorship that were close to, if not exactly the</p> <p>20 same as, what's in this form? 02:48</p> <p>21 A. Yes. These were available on our line</p> <p>22 free to anybody in the world.</p> <p>23 MR. MONTGOMERY: I'd like to ask the</p> <p>24 Court Reporter to mark Exhibit 37.</p>	<p>96</p> <p>1 it's for the methodology, very common, because you 02:50</p> <p>2 already know what you did. After that it is</p> <p>3 gutsy.</p> <p>4 Q. In your opinion would it be</p> <p>5 scientifically appropriate to draft a fill in the 02:50</p> <p>6 blanks for all of the analysis?</p> <p>7 MR. HALPER: Objection to form.</p> <p>8 THE WITNESS: Well, it depends. I mean</p> <p>9 at this point if they knew how many patients were</p> <p>10 in there and all that kind, they were sort of, 02:50</p> <p>11 they weren't quite sure if it was going to be</p> <p>12 plus/minus ten because you leave a blank for</p> <p>13 patients entered and this kind of stuff, but when</p> <p>14 it gets to anything beyond how many patients did</p> <p>15 this, this, or this and what the statistical 02:50</p> <p>16 analysis was, that is gutsy. It's very unusual.</p> <p>17 I don't know how they could write it.</p> <p>18 MR. MONTGOMERY: I'd like to ask the</p> <p>19 Court Reporter to mark what will be Exhibit 38.</p> <p>20 (WHEREUPON Deposition Exhibit 02:51</p> <p>21 No. 38 was marked as of</p> <p>22 1/12/2007.)</p> <p>23 THE WITNESS: Sir, may I ask who Nancy</p> <p>24 Tam is, or is that not appropriate?</p>

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<p>97</p> <p>1 MR. MONTGOMERY: You can ask anything 02:51</p> <p>2 you want, but I don't know the answer.</p> <p>3 BY MR. MONTGOMERY:</p> <p>4 Q. Do you want me to give you an idea of</p> <p>5 where we're going so you might know what sections 02:54</p> <p>6 to read? Once I ask you a question if you need to</p> <p>7 read some more of it --</p> <p>8 A. No. I don't need to read anymore.</p> <p>9 Q. Having flipped through it, does this</p> <p>10 appear to be a sort of an example of the fill in 02:54</p> <p>11 the blanks type of manuscript we just discussed?</p> <p>12 A. Yes.</p> <p>13 MR. HALPER: Objection to form, calls</p> <p>14 for speculation.</p> <p>15 BY MR. MONTGOMERY: 02:54</p> <p>16 Q. Would you turn to page what is Bates</p> <p>17 No. 910 ending. Looking at this page, does it</p> <p>18 appear that defendants applied the fill in the</p> <p>19 blanks methodology to the results of the study at</p> <p>20 this point? 02:54</p> <p>21 MR. HALPER: Objection to form, calls</p> <p>22 for speculation.</p> <p>23 THE WITNESS: Figure 1, that's okay. I</p> <p>24 mean you know that you, like I said, you just put</p>	<p>99</p> <p>1 would you have then understood that the study 02:56</p> <p>2 lasted longer than six months?</p> <p>3 A. Oh, yes.</p> <p>4 Q. Please turn to page Bates number ending</p> <p>5 899 of Exhibit 38. Do you see under Methods? 02:56</p> <p>6 A. Yes.</p> <p>7 Q. The first sentence reads "Patients with</p> <p>8 OA or RA were enrolled into one of two studies</p> <p>9 simultaneously conducted for a period up to</p> <p>10 sixty-five weeks." Do you see that? 02:57</p> <p>11 A. Yes.</p> <p>12 Q. And reading that, would you understand</p> <p>13 that the study lasted longer than six months?</p> <p>14 A. Yes.</p> <p>15 Q. And had the authors included that in the 02:57</p> <p>16 JAMA article, would you have understood that the</p> <p>17 study lasted longer than six months?</p> <p>18 A. Yes.</p> <p>19 Q. All right. I'd like you to turn back to</p> <p>20 Exhibit 31 briefly. That is the letter to JAMA. 02:57</p> <p>21 It's Exhibit 31.</p> <p>22 On the first page there's a section</p> <p>23 that says Guidelines For Letters in the lower</p> <p>24 right-hand corner. Do you see Guidelines For</p>
<p>98</p> <p>1 in the number, and the figure is a standard figure 02:55</p> <p>2 you use for this sort of study. But then when you</p> <p>3 get down into some of the other stuff, it's gutsy.</p> <p>4 BY MR. MONTGOMERY:</p> <p>5 Q. Would you turn to page ending Bates 02:55</p> <p>6 No. 905. Do you see Outcome Measures on that</p> <p>7 page?</p> <p>8 A. Yes.</p> <p>9 Q. The first sentence there reads "The</p> <p>10 primary endpoint was the incidence of upper GI 02:56</p> <p>11 ulcer complications during the period of drug</p> <p>12 administration (up to sixty-five weeks)." Do you</p> <p>13 see that?</p> <p>14 A. Uh-huh.</p> <p>15 Q. Does this indicate that the analysis in 02:56</p> <p>16 this manuscript was for the entire study period</p> <p>17 and not just the first six months?</p> <p>18 A. Yes.</p> <p>19 Q. And if that language had been included</p> <p>20 in the JAMA article, would you have understood 02:56</p> <p>21 that the study lasted longer than six months?</p> <p>22 A. Would I --</p> <p>23 Q. If that same language that I just read</p> <p>24 to you had been included in the JAMA article,</p>	<p>100</p> <p>1 Letters? 02:58</p> <p>2 A. Yes.</p> <p>3 Q. And then in that it says "A signed</p> <p>4 statement for authorship criteria and</p> <p>5 responsibility, financial disclosure, copyright 02:58</p> <p>6 transfer, and acknowledgment is required for</p> <p>7 publication."</p> <p>8 A. Yes.</p> <p>9 Q. Is that the same sort of disclosure or</p> <p>10 form that we just looked at for authors of 02:58</p> <p>11 articles?</p> <p>12 A. Yes, except most letters are in response</p> <p>13 to something. So if they say there was no data</p> <p>14 collected, then that's okay. I mean you'd look at</p> <p>15 it differently, but the expectation is that 02:58</p> <p>16 everyone who signs would meet certain criteria for</p> <p>17 the letters and that they, for example, either</p> <p>18 part or whole of the content, concept, and design,</p> <p>19 you wouldn't expect data necessarily. Drafting</p> <p>20 the manuscript or critical revision and important 02:59</p> <p>21 intellectual content, those sorts of things all</p> <p>22 have to be in there and the rest has to be.</p> <p>23 MR. MONTGOMERY: I'd like to ask the</p> <p>24 Court Reporter to mark what will be Exhibit 39.</p>

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<p>101</p> <p>1 (WHEREUPON Deposition Exhibit 02:59 2 No. 39 was marked as of 3 1/12/2007.) 4 BY MR. MONTGOMERY: 5 Q. For the record, Exhibit 39 is an e-mail 02:59 6 string starting with an e-mail from Goran, 7 G-O-R-A-N, Ando, A-N-D-O, to Philip Needleman and 8 several others dated August 13, 2001. (Document 9 tendered to the witness.) 10 I'm just going to ask you about the 02:59 11 top e-mail, but you can read as much as you'd 12 like. And the subject heading is "Re: JAMA 13 Letters to the Editor." 14 In that paragraph do you see where 15 it says "Once we redraft the letter, we would send 03:00 16 it to the authors and get their buy-in with the 17 intent on making the ten day timeline imposed by 18 JAMA." Do you see that? 19 A. Yes. 20 Q. If all the purported authors of the 03:00 21 letter to JAMA did was buy into a letter that was 22 drafted by someone else, would that meet the 23 authorship criteria that JAMA had at the time? 24 MR. HALPER: Objection to form.</p>	<p>103</p> <p>1 A. Yes. 03:02 2 MR. MONTGOMERY: I'd like to ask the 3 Court Reporter to mark what will be Exhibit 40. 4 (WHEREUPON Deposition Exhibit 5 No. 40 was marked as of 03:02 6 1/12/2007.) 7 BY MR. MONTGOMERY: 8 Q. For the record, Exhibit 40 is an 9 editorial from JAMA dated July 12, 2006. 10 (Document tendered to the witness.) 03:02 11 Were you one of the authors of 12 Exhibit 40? 13 A. Yes. And I met all the qualifications 14 and I signed the form. 15 Q. Does this article or editorial 03:03 16 memorialize the changes in the conflict of 17 interest policy that you described earlier? 18 A. Yes. 19 Q. And was the JAMA article that we have 20 been discussing one of the reasons why JAMA 03:03 21 changed its conflict of interest policy? 22 A. There were many reasons, but that was 23 one of many. 24 MR. MONTGOMERY: I'd like to ask the</p>
<p>102</p> <p>1 THE WITNESS: It would meet perhaps the 03:00 2 criteria; however, it is what we call ghost 3 writing. And that is, the people who should have 4 been an author, their names weren't there. 5 Because anyone who meets these criteria should be 03:01 6 an author because they met the criteria for an 7 author. 8 Occasionally there will be people 9 who make significant contributions to manuscript 10 and you see them in the acknowledgments, but it is 03:01 11 stated what that person did. If we receive 12 material that is obviously ghost written by 13 someone, we will not publish it. 14 BY MR. MONTGOMERY: 15 Q. So in other words, under JAMA's 03:01 16 requirements it's mandatory for anybody that meets 17 the requirements of authorship to be listed as an 18 author? 19 A. That's the expectation. 20 Q. So if the letter to JAMA in Exhibit 31 03:02 21 that we talked about earlier was drafted by 22 somebody at the company and simply approved by the 23 listed authors, then that person should have been 24 listed as an author?</p>	<p>104</p> <p>1 Court Reporter to mark what will be Exhibit 41. 03:03 2 (WHEREUPON Deposition Exhibit 3 No. 41 was marked as of 4 1/12/2007.) 5 BY MR. MONTGOMERY: 03:03 6 Q. For the record, Exhibit 41 is another 7 editorial from JAMA dated August 23/30, 2006. 8 (Document tendered to the witness.) 9 A. We do a double issue at the end of the 10 month. We do four issues a month. 03:04 11 Q. I see. 12 Did you write Exhibit 41 as well? 13 A. Yes. 14 Q. Why did you write Exhibit 41? 15 A. To make it as clear as possible to our 03:04 16 readers, authors, and reviewers of course I 17 consider our readers, exactly what I thought was 18 going on as far as money influencing what 19 physicians, clinical scientists, institutions, how 20 money was influencing what they did, which I 03:05 21 thought was wrong. 22 It was an advent to some very, it 23 was an explanation of why we were coming down hard 24 on conflict of interest. People had misconstrued</p>

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<p style="text-align: right;">105</p> <p>1 why we kept publishing letters of apology from 03:05</p> <p>2 people when we found that they did not disclose</p> <p>3 things. And instead of people understanding that</p> <p>4 we weren't just publishing a correction, which is</p> <p>5 what every other journal does, I decided that we 03:06</p> <p>6 were going to make a big deal out of it. And</p> <p>7 people misunderstood that we were being duped and</p> <p>8 it was just the opposite, and I said I'm not going</p> <p>9 to tolerate it. So if you don't disclose, we're</p> <p>10 going to reveal it and we're going to make you 03:06</p> <p>11 apologize to our readers, because it's the readers</p> <p>12 who they apologize to, not to us.</p> <p>13 Q. All right. On the first page of Exhibit</p> <p>14 41, at the top of the right-hand column, you have</p> <p>15 a list of different events. 03:06</p> <p>16 A. Yes.</p> <p>17 Q. One of them says "reporting only six</p> <p>18 months of data in a trial designed to have twelve</p> <p>19 months of data as the primary outcome."</p> <p>20 A. Yes. 03:06</p> <p>21 Q. Does that refer to the JAMA article</p> <p>22 we've been discussing?</p> <p>23 A. The CLASS study, yes. It's referenced.</p> <p>24 Q. Once again, so that was one of the</p>	<p style="text-align: right;">107</p> <p>1 studies," in the middle of that paragraph there's 03:08</p> <p>2 a sentence that begins "In this issue of The</p> <p>3 Journal," do you see that?</p> <p>4 A. Yes.</p> <p>5 Q. All right. I'm going to read it into 03:08</p> <p>6 the record. It says "In this issue of The</p> <p>7 Journal, Silverstein, et al., report the results</p> <p>8 of a six-month randomized, double-blind,</p> <p>9 controlled trial comparing the ulcerogenic</p> <p>10 potential and upper GI toxicity of celecoxib in 03:09</p> <p>11 individuals with osteoarthritis or rheumatoid</p> <p>12 arthritis."</p> <p>13 Is the description of the CLASS</p> <p>14 study as a six-month trial there accurate in your</p> <p>15 understanding? 03:09</p> <p>16 A. That was our understanding at the time.</p> <p>17 That was the understanding of the editor. He was</p> <p>18 given the manuscript that we were to publish and</p> <p>19 he read it and this is what he took, this is his</p> <p>20 analysis of what we gave him. 03:09</p> <p>21 Q. My question is now with the benefit of</p> <p>22 hindsight knowing what you know, is that</p> <p>23 description of the CLASS study accurate?</p> <p>24 A. No.</p>
<p style="text-align: right;">106</p> <p>1 reasons, one of the reasons, why you changed -- 03:07</p> <p>2 A. Yes.</p> <p>3 Q. -- JAMA's conflict of interest policy?</p> <p>4 A. Yes.</p> <p>5 Q. I'd like to show the witness what's been 03:07</p> <p>6 previously marked as Exhibit 4. (Document</p> <p>7 tendered to the witness.)</p> <p>8 For the record, Exhibit 4 is an</p> <p>9 editorial from the September 13, 2000 issue of</p> <p>10 JAMA entitled COX-2-Selective NSAIDs, New and 03:07</p> <p>11 Improved?"</p> <p>12 Is this an editorial from the</p> <p>13 September 13, 2000 issue?</p> <p>14 A. Yes. It was specifically so elicited as</p> <p>15 the companion piece to the CLASS study. 03:08</p> <p>16 Q. Who solicited this editorial?</p> <p>17 A. We did, I did ultimately. I can't</p> <p>18 remember who made the call.</p> <p>19 Q. Did the authors of the JAMA article have</p> <p>20 an opportunity to see this editorial before it was 03:08</p> <p>21 published?</p> <p>22 A. No.</p> <p>23 Q. On the first page of Exhibit 4, the</p> <p>24 second column, the paragraph starting "Previous</p>	<p style="text-align: right;">108</p> <p>1 Q. And why is that? 03:10</p> <p>2 A. Because it was a study that took twelve</p> <p>3 months, actually more than twelve months, to reach</p> <p>4 its planned endpoint of forty GI episodes of</p> <p>5 bleeding. It was a twelve-month study. 03:10</p> <p>6 MR. MONTGOMERY: I'd like to ask the</p> <p>7 Court Reporter to mark what will be Exhibit 42.</p> <p>8 (WHEREUPON Deposition Exhibit</p> <p>9 No. 42 was marked as of</p> <p>10 1/12/2007.) 03:10</p> <p>11 BY MR. MONTGOMERY:</p> <p>12 Q. Do you recognize Exhibit 42? (Document</p> <p>13 tendered to the witness.)</p> <p>14 A. I recognize this part and I recognize</p> <p>15 that part. 03:11</p> <p>16 Q. Meaning the first and third pages of</p> <p>17 Exhibit 42?</p> <p>18 A. Yes, excuse me, yes, the first and third</p> <p>19 page of what you handed me.</p> <p>20 Q. Do you recognize the second page? 03:11</p> <p>21 A. No. I mean may I ask where it came</p> <p>22 from?</p> <p>23 Q. Your attorney produced it to me.</p> <p>24 MR. NELSON: There's another deponent</p>

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<p>109</p> <p>1 besides you, Dr. DeAngelis. 03:11</p> <p>2 THE WITNESS: I'm sorry?</p> <p>3 MR. NELSON: You're the witness today</p> <p>4 but there's going to be another witness in this</p> <p>5 case from the AMA. 03:12</p> <p>6 THE WITNESS: Excuse me.</p> <p>7 MR. MONTGOMERY: That's fine. If you</p> <p>8 don't recognize it, you don't recognize it. Not a</p> <p>9 problem.</p> <p>10 BY MR. MONTGOMERY: 03:12</p> <p>11 Q. All right. We talked before, is it</p> <p>12 correct to say that you first found out about the</p> <p>13 post six-month data from the FDA website around</p> <p>14 February of 2001?</p> <p>15 A. I found out about the first six-month -- 03:12</p> <p>16 Q. The post six-month data.</p> <p>17 A. Oh, the post, excuse me. It came from,</p> <p>18 and I recognize Dr. Wright because you produced</p> <p>19 something that jogged my memory, he was the one</p> <p>20 who called me because he said, he admitted it 03:12</p> <p>21 there, and I remember he was the one who called.</p> <p>22 That's when I was told. I invited him to write a</p> <p>23 letter to the editor, as I did the other two, and</p> <p>24 went to the website and they were accurate,</p>	<p>111</p> <p>1 for speculation. 03:14</p> <p>2 THE WITNESS: I know that by choosing</p> <p>3 that, there had to be a reason. And when you look</p> <p>4 at the end of twelve months and you see there's no</p> <p>5 difference, but when you look at six months and 03:15</p> <p>6 you see a difference, it made logical sense to me</p> <p>7 that you'd choose this because it had a result</p> <p>8 that made a product look like it was something</p> <p>9 that was a better product to use because it had</p> <p>10 less GI bleeding. Whereas, if you had gone to the 03:15</p> <p>11 endpoint there was no difference. It was no</p> <p>12 worse. It was just no better as far as GI</p> <p>13 bleeding goes.</p> <p>14 BY MR. MONTGOMERY:</p> <p>15 Q. We went through several articles, these 03:15</p> <p>16 articles today, but I noticed that in the</p> <p>17 August 2001 Washington Post, for example, do you</p> <p>18 recall we looked at your language where you said</p> <p>19 we were functioning at a level of trust that was</p> <p>20 perhaps broken, do you recall that? 03:15</p> <p>21 A. Yes.</p> <p>22 Q. And then do you recall the other</p> <p>23 articles that we looked at from let's say 2005</p> <p>24 2006 where your language was the authors lied?</p>
<p>110</p> <p>1 Dr. Wright and the other two writers were 03:13</p> <p>2 accurate.</p> <p>3 Q. As of February 2001, so I'm asking you</p> <p>4 about your thought process at that time --</p> <p>5 A. February 2001. 03:13</p> <p>6 Q. Right, at the time you found out about</p> <p>7 the data on the FDA website.</p> <p>8 A. Yes.</p> <p>9 Q. As of February 2001, did you know that</p> <p>10 the authors of the JAMA article had cherry-picked 03:13</p> <p>11 data?</p> <p>12 A. After I went to the -- I'm not sure I</p> <p>13 would use the word "cherry-picked." It isn't in</p> <p>14 my vernacular usually.</p> <p>15 It was clear to me that what was 03:13</p> <p>16 presented to us was not this CLASS study, and that</p> <p>17 the data that were presented to us had been</p> <p>18 analyzed in a way that was quite peculiar.</p> <p>19 Q. But as of February 2001, did you know</p> <p>20 even after you saw the data that the authors of 03:14</p> <p>21 the JAMA article had chosen the first six months</p> <p>22 of data for no reason other than it made Celebrex</p> <p>23 look better?</p> <p>24 MR. HALPER: Objection to form and calls</p>	<p>112</p> <p>1 A. Yes. 03:16</p> <p>2 Q. Can you explain to me why your portrayal</p> <p>3 of their conduct, why you characterized their</p> <p>4 conduct differently from 2001 to 2005?</p> <p>5 A. Because after I read their description 03:16</p> <p>6 of why they had done what they did, I thought that</p> <p>7 we had been, we had been given misinformation and</p> <p>8 the only way I could think about it, and believe</p> <p>9 me, I've thought long and hard about this one, was</p> <p>10 that it had to be a lie because what they 03:17</p> <p>11 presented was not the CLASS study data. It was</p> <p>12 specific data chosen for a reason.</p> <p>13 Now, they may have presented the</p> <p>14 data to me in that way as six months and describe</p> <p>15 their reasoning for doing it that way. Had they 03:17</p> <p>16 done that, I probably, well, I know I wouldn't</p> <p>17 have published it, but it would have been the same</p> <p>18 data but with the explanation that it was six</p> <p>19 months and not twelve and why they had done it and</p> <p>20 I just wouldn't have bought it. I would have 03:17</p> <p>21 thought no, show me what happens when you get to</p> <p>22 twelve months.</p> <p>23 But the six month, that's probably</p> <p>24 an accurate way to look at it. But the twelve</p>



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<p>113</p> <p>1 month data, which is their endpoint to get the 03:18</p> <p>2 forty-four bleeding, well, they had forty, forty</p> <p>3 was their endpoint, they actually end up to</p> <p>4 forty-four, I'm pretty sure it was forty-four,</p> <p>5 showed there was no difference. That's the 03:18</p> <p>6 endpoint of CLASS, not this.</p> <p>7 And what they lied to me was I have</p> <p>8 documentation, e-mail, this was a six-month study.</p> <p>9 And it was not. That is a lie.</p> <p>10 Q. When you say your opinion of the 03:18</p> <p>11 authors' conduct changed when you read their</p> <p>12 written explanation, are you referring to the JAMA</p> <p>13 letter that's in Exhibit 31?</p> <p>14 A. The letter in reply.</p> <p>15 Q. Right. So let's just make sure. 03:18</p> <p>16 Take a look at Exhibit 31 to make</p> <p>17 sure we're dealing with the same thing.</p> <p>18 A. Yes. It's the one, yes, it's 31, second</p> <p>19 page in reply, "In retrospect."</p> <p>20 Q. So just to summarize: In February of 03:19</p> <p>21 2001, you learned about the post six-month data</p> <p>22 from the FDA's website; is that correct?</p> <p>23 A. Yes.</p> <p>24 Q. But it wasn't until --</p>	<p>115</p> <p>1 record. 03:20</p> <p>2 THE VIDEOGRAPHER: All right. This will</p> <p>3 conclude Videotape No. 3 of the videotaped</p> <p>4 deposition, the deposition of Ms. DeAngelis. We</p> <p>5 will continue on Videotape No. 4. The time now is 03:20</p> <p>6 approximately 3:20.</p> <p>7 (WHEREUPON a recess was taken.)</p> <p>8 THE VIDEOGRAPHER: This will begin</p> <p>9 Videotape No. 4 of the videotaped deposition of</p> <p>10 Catherine DeAngelis taken in the matter of Case 03:34</p> <p>11 No. 03-1519. Today is the 12th day of January,</p> <p>12 2007. The time now is approximately 3:34 p.m.,</p> <p>13 and I will remind the witness she remains under</p> <p>14 oath.</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
<p>114</p> <p>1 A. Well, I learned about it from the 03:19</p> <p>2 letters and then went to the site.</p> <p>3 Q. But it wasn't until you read the</p> <p>4 authors' written explanation in JAMA that was</p> <p>5 published November 21, 2001, that you concluded 03:19</p> <p>6 that they had lied; is that correct?</p> <p>7 A. Yes, because their explanation, in</p> <p>8 retrospect we acknowledge we could have avoided</p> <p>9 confusion by explaining why we chose to inform.</p> <p>10 We ask them. We didn't ask them to 03:20</p> <p>11 explain why they did it, we ask them is this a</p> <p>12 six-month or do you have more data, and they said</p> <p>13 this is a six-month study.</p> <p>14 MR. MONTGOMERY: All right. I have --</p> <p>15 THE WITNESS: That's not what that says. 03:20</p> <p>16 MR. MONTGOMERY: I have no more</p> <p>17 questions for now. Although I undoubtedly will</p> <p>18 want to follow up after defendants have had an</p> <p>19 opportunity to question you.</p> <p>20 Do you want to go off the record 03:20</p> <p>21 first?</p> <p>22 MR. HALPER: I do. I need a few</p> <p>23 minutes.</p> <p>24 MR. MONTGOMERY: Sure. Let's go off the</p>	<p>116</p> <p>1 EXAMINATION 03:34</p> <p>2 BY MR. HALPER:</p> <p>3 BY MR. HALPER:</p> <p>4 Q. Good afternoon, Dr. DeAngelis.</p> <p>5 A. Hi. 03:34</p> <p>6 Q. You testified this morning that the</p> <p>7 first time you became aware of the CLASS study was</p> <p>8 when you attended a manuscript meeting. Do you</p> <p>9 recall that?</p> <p>10 A. Yes. 03:34</p> <p>11 Q. Do you recall how long that meeting</p> <p>12 lasted?</p> <p>13 A. Well, the meetings last several hours,</p> <p>14 but we discuss many manuscripts.</p> <p>15 Q. Approximately how long did you discuss 03:35</p> <p>16 the CLASS manuscript?</p> <p>17 A. I don't recall.</p> <p>18 Q. Less than half an hour?</p> <p>19 A. Probably.</p> <p>20 Q. About fifteen minutes? 03:35</p> <p>21 A. Probably closer to a half hour. But</p> <p>22 this is the summation of many persons' input into</p> <p>23 this. This is not just that's the first time</p> <p>24 anybody discussed. This is after it has been</p>

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<p style="text-align: right;">117</p> <p>1 reviewed, sometimes re-reviewed, and the 03:35</p> <p>2 presentation is by someone who's been living with</p> <p>3 this manuscript for a long time, and I have the</p> <p>4 full manuscript in front of me.</p> <p>5 Q. Understood. 03:35</p> <p>6 But those reviews and re-reviews</p> <p>7 were not done by you; is that correct?</p> <p>8 A. No.</p> <p>9 Q. They were done by other people at JAMA?</p> <p>10 A. They were done by, no, they were done by 03:35</p> <p>11 our peer reviewers, people with expertise in the</p> <p>12 field and statisticians.</p> <p>13 Q. Thank you.</p> <p>14 And the first time you became aware</p> <p>15 of the study was at this manuscript meeting? 03:36</p> <p>16 A. The first time I became aware of the</p> <p>17 study report. I knew there was this study going</p> <p>18 on, but I wasn't sure what it was or anything like</p> <p>19 that. People, you know, talk about all different</p> <p>20 kinds of studies going on. 03:36</p> <p>21 Q. Your first substantive involvement --</p> <p>22 A. Yes.</p> <p>23 Q. -- was at this manuscript meeting; is</p> <p>24 that correct?</p>	<p style="text-align: right;">119</p> <p>1 A. I asked her to please, she had discussed 03:37</p> <p>2 this with Dr. Silverstein and he had said that</p> <p>3 this was the full data, it was six months, and I</p> <p>4 said look, make sure that you and I can't recall,</p> <p>5 that was probably after the second manuscript, 03:37</p> <p>6 make sure that you put in writing so he</p> <p>7 understands exactly what you're talking about,</p> <p>8 what Dr. Lichtenstein meant, is this as it's</p> <p>9 presented a six-month study or are there more data</p> <p>10 on these patients, and she did that. 03:38</p> <p>11 Q. Let's just make sure we're talking about</p> <p>12 the right person.</p> <p>13 Do you understand Dr. Winker to</p> <p>14 have been talking to the corresponding author?</p> <p>15 A. Yes. 03:38</p> <p>16 Q. And I think you referred earlier to that</p> <p>17 person as Dr. Lefkowitz?</p> <p>18 A. Yeah. I'm not sure if she speak with</p> <p>19 Dr. Silverstein or Dr. Lefkowitz. It may have</p> <p>20 been either one of them on the phone. And she 03:38</p> <p>21 can't recall, I asked her and she said, you know,</p> <p>22 this is a long time ago, we do five thousand</p> <p>23 manuscripts a year. She spoke to someone, but she</p> <p>24 can't recall exactly what the words were.</p>
<p style="text-align: right;">118</p> <p>1 A. Correct. 03:36</p> <p>2 Q. The next time you focused on the CLASS</p> <p>3 manuscript was at a subsequent manuscript meeting;</p> <p>4 is that correct?</p> <p>5 A. Yes, with some hallway discussions with 03:36</p> <p>6 Dr. Winker in between.</p> <p>7 Q. When you say "hallway discussions," do I</p> <p>8 take it those were not formal meetings with her?</p> <p>9 A. No, right.</p> <p>10 Q. You would run into her in the hallway 03:36</p> <p>11 and mention something?</p> <p>12 A. Our offices are in the same area. We</p> <p>13 talk all the time. We see each other, we discuss</p> <p>14 many, many things.</p> <p>15 Q. Do you remember any of the content of 03:37</p> <p>16 those hallway discussions?</p> <p>17 A. Mostly it had to do with the discussion</p> <p>18 about six month, twelve month, is this</p> <p>19 preliminary, the whole business. In fact, we even</p> <p>20 discussed maybe there should be a preliminary 03:37</p> <p>21 communication rather than a full, that kind of</p> <p>22 stuff.</p> <p>23 Q. What did she tell you as best you recall</p> <p>24 regarding the six and twelve month issue?</p>	<p style="text-align: right;">120</p> <p>1 Q. At the second manuscript meeting where 03:38</p> <p>2 you discussed CLASS --</p> <p>3 A. Yes.</p> <p>4 Q. -- how much time in that meeting did you</p> <p>5 focus on that manuscript? 03:39</p> <p>6 A. Probably about the same amount of time.</p> <p>7 Q. And in either of those manuscript</p> <p>8 meetings did you have any written work product in</p> <p>9 front of you besides the manuscript?</p> <p>10 A. Like what? 03:39</p> <p>11 Q. If there's nothing, that's fine. My</p> <p>12 only question is besides the manuscript, was</p> <p>13 anything else discussed at either of the</p> <p>14 manuscript meetings?</p> <p>15 A. Pertaining to the CLASS study? 03:39</p> <p>16 Q. Yes.</p> <p>17 A. No.</p> <p>18 Q. Did you discuss the CLASS manuscript at</p> <p>19 any subsequent manuscript meetings?</p> <p>20 A. No. 03:39</p> <p>21 Q. So prior to publication your involvement</p> <p>22 in the CLASS manuscript consisted of your</p> <p>23 participation in the two manuscript meetings and</p> <p>24 your hallway conversations with Dr. Winker; is</p>

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<p style="text-align: right;">121</p> <p>1 that correct? 03:39</p> <p>2 A. Several ongoing discussions, especially</p> <p>3 when we got the response in writing on e-mail. We</p> <p>4 went back and forth about what do we do with this.</p> <p>5 So there were a lot of ongoing discussions. 03:40</p> <p>6 We discuss manuscripts all the</p> <p>7 time, and I don't recall how much time or when or</p> <p>8 where, but some time in between the second</p> <p>9 manuscript meeting where we decided that we would</p> <p>10 take this study and publish it but we had to be 03:40</p> <p>11 sure that this was the end of the study. And if</p> <p>12 you look at the edited, the copy edited manuscript</p> <p>13 that was sent to Dr. Lefkowitz, there are specific</p> <p>14 questions about is this the whole, I don't know</p> <p>15 the exact wording, I don't have it here with me, I 03:41</p> <p>16 have it somewhere else, but is this a six-month</p> <p>17 study, is that what you said, is this a six-month</p> <p>18 study, is that true, what about the others, is</p> <p>19 there other information. And the response was you</p> <p>20 are correct, this is the study, it's complete. 03:41</p> <p>21 And there were several e-mails back and forth</p> <p>22 between Dr. Winker and Dr. Lefkowitz, and he said</p> <p>23 there is longer data on the patients, they can</p> <p>24 remain in the study if they want to, but this is</p>	<p style="text-align: right;">123</p> <p>1 MR. NELSON: The JAMA article? Is that 03:43</p> <p>2 what you're talking about?</p> <p>3 THE WITNESS: Yes. I've got it.</p> <p>4 BY MR. BROWN:</p> <p>5 Q. If you turn to the third page, the 03:43</p> <p>6 second full paragraph.</p> <p>7 A. "All documentation"?</p> <p>8 Q. The next paragraph.</p> <p>9 A. "Adverse"?</p> <p>10 Q. Right. Do you want me to read it to 03:43</p> <p>11 you?</p> <p>12 A. Yes.</p> <p>13 Q. "Adverse effect data were collected at</p> <p>14 each visit and as reported spontaneously using the</p> <p>15 following question: Since your last visit have 03:43</p> <p>16 you experienced or do you currently have any</p> <p>17 symptoms that are not associated with your</p> <p>18 arthritis." Do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. Doesn't that disclose that data was 03:43</p> <p>21 being collected for as long as a patient remained</p> <p>22 in the study?</p> <p>23 A. Not necessarily. If somebody tells me</p> <p>24 this is a six-month study, what they do outside</p>
<p style="text-align: right;">122</p> <p>1 the six-month study. 03:41</p> <p>2 Q. So you knew there was longer data beyond</p> <p>3 the six months?</p> <p>4 A. I knew there were more data on some</p> <p>5 patients who might have wanted to be studied 03:42</p> <p>6 further. But the study protocol, the study was a</p> <p>7 six-month study. We specifically asked that.</p> <p>8 Q. But those are two different things;</p> <p>9 correct?</p> <p>10 A. No, they're not. The study is what we 03:42</p> <p>11 were reporting.</p> <p>12 Q. On the issue of whether there was data</p> <p>13 available for at least some patients for more than</p> <p>14 six months you knew that there in fact was?</p> <p>15 A. I didn't know there were data. I didn't 03:42</p> <p>16 know they had the data because once they said</p> <p>17 yeah, we were following them through, I thought</p> <p>18 maybe the company wants to know what happens</p> <p>19 longer. The study was completed at six months.</p> <p>20 That was made clear in writing back and forth 03:42</p> <p>21 questions.</p> <p>22 Q. Okay. If you turn to what was the JAMA</p> <p>23 publication, so previously marked as Exhibit 3.</p> <p>24 A. I'm sorry. Which exhibit was it?</p>	<p style="text-align: right;">124</p> <p>1 the study is not what I'm concerned about. I'm 03:44</p> <p>2 concerned about what is in the study. This was</p> <p>3 presented as the CLASS study, a randomized</p> <p>4 controlled trial. This is not the CLASS study</p> <p>5 that was reported to us. 03:44</p> <p>6 Q. On Page 2 if you look at the study</p> <p>7 protocol section.</p> <p>8 A. Okay.</p> <p>9 Q. And I think this was read to you</p> <p>10 earlier. The last two sentences in the first 03:44</p> <p>11 paragraph in the study protocol section in the</p> <p>12 manuscript says "After a baseline visit, follow-up</p> <p>13 clinic visits took place at Weeks 4, 13, and 26</p> <p>14 after the initial dose of medication and every</p> <p>15 thirteen weeks thereafter. All patients were 03:44</p> <p>16 provided an opportunity to complete a minimum of</p> <p>17 six months of treatment." Do you see that?</p> <p>18 A. I saw that.</p> <p>19 Q. And that's in the study protocol section</p> <p>20 in the manuscript; correct? 03:45</p> <p>21 A. Right. That's what stimulated our</p> <p>22 queries about this is a six-month study? And what</p> <p>23 we were told was the CLASS study is a six-month</p> <p>24 study. I have it in writing.</p>

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<p>125</p> <p>1 Q. But my question is more narrow. 03:45</p> <p>2 A. And we asked them -- you see, a study</p> <p>3 can go on, for example, you have a study that's</p> <p>4 finished and then you do post ongoing studies to</p> <p>5 see, you may contact the patient, who knows how 03:45</p> <p>6 often. That's not part of the study.</p> <p>7 Q. But it's in the study protocol section.</p> <p>8 A. Right. But when we ask, see, this is</p> <p>9 why, the answer, if I have that here and I could</p> <p>10 produce it if you want. 03:46</p> <p>11 MR. NELSON: He has it.</p> <p>12 THE WITNESS: Okay. Specifically says,</p> <p>13 the answer, if the patients want. This is a</p> <p>14 six-month study. Anything after the six months</p> <p>15 would be if the patients want to continue, that's 03:46</p> <p>16 fine.</p> <p>17 BY MR. HALPER:</p> <p>18 Q. Putting aside what you just testified to</p> <p>19 being told, what is written here in the study</p> <p>20 protocol section discloses, does it not, that part 03:46</p> <p>21 of the study protocol was following up and</p> <p>22 collecting patient data after six months?</p> <p>23 MR. MONTGOMERY: Objection. The</p> <p>24 document speaks for itself.</p>	<p>127</p> <p>1 Q. So prior to this being published, again, 03:48</p> <p>2 you didn't speak to any of these seventeen</p> <p>3 individuals?</p> <p>4 A. No.</p> <p>5 Q. And as far as you know, Dr. Winker only 03:48</p> <p>6 spoke with the corresponding author; is that</p> <p>7 correct?</p> <p>8 A. Yes.</p> <p>9 Q. Do you have any reason to believe anyone</p> <p>10 else at JAMA spoke with anyone, any of the other 03:48</p> <p>11 authors?</p> <p>12 A. No. They would have no reason to, and</p> <p>13 it would be improper for them to do so without</p> <p>14 Dr. Winker and I knowing it.</p> <p>15 Q. Following the publication of the 03:48</p> <p>16 article, did you personally speak to any of the</p> <p>17 seventeen authors?</p> <p>18 A. You know, I don't recall. I remember,</p> <p>19 see, this is where I can't remember if when I</p> <p>20 called I wanted to speak with Dr. Silverstein, he 03:49</p> <p>21 was the one I wanted to talk to, and I kept</p> <p>22 getting responses from --</p> <p>23 Q. I'll tell you in that meeting --</p> <p>24 A. Dr. --</p>
<p>126</p> <p>1 THE WITNESS: It was this statement in 03:47</p> <p>2 the protocol that stimulated our questioning where</p> <p>3 are those data, and we were told this is a</p> <p>4 six-month study. Patients were followed</p> <p>5 thereafter if they wanted to. 03:47</p> <p>6 BY MR. HALPER:</p> <p>7 Q. Is that what this says?</p> <p>8 A. That's not what this says. It's what</p> <p>9 the authors responded to us when we queried.</p> <p>10 Q. But I'm asking a different question. 03:47</p> <p>11 A. Okay.</p> <p>12 Q. The statement here in the study protocol</p> <p>13 section of the manuscript discloses that the study</p> <p>14 protocol involved following up patients after six</p> <p>15 months; is that true? 03:47</p> <p>16 A. Yes.</p> <p>17 Q. Other than speaking to Dr. Winker prior</p> <p>18 to the manuscript being published, did you</p> <p>19 personally speak to any of the seventeen authors</p> <p>20 listed here? 03:48</p> <p>21 A. No. That's not standard procedure.</p> <p>22 Q. That's fine. I'm not challenging. I'm</p> <p>23 just asking, okay.</p> <p>24 A. Right.</p>	<p>128</p> <p>1 Q. Verburg. 03:49</p> <p>2 A. Pardon?</p> <p>3 Q. You met with Dr. Verburg.</p> <p>4 A. Verburg -- no, it wasn't Dr. Verburg.</p> <p>5 It was Dr. Friedman. And that's why I agreed to 03:49</p> <p>6 meet with them assuming that Dr. Silverstein would</p> <p>7 be with them. I never spoke with Dr. or even knew</p> <p>8 about Dr. Verburg before he came to this meeting.</p> <p>9 That was the first time that I had ever met him or</p> <p>10 spoke to him. 03:50</p> <p>11 Q. Did you ever speak with him after that</p> <p>12 meeting?</p> <p>13 A. Not to my knowledge. I don't remember</p> <p>14 speaking with him.</p> <p>15 Q. Did you ever speak with Dr. Silverstein 03:50</p> <p>16 regarding this publication?</p> <p>17 A. I spoke to him thereafter, but I can't,</p> <p>18 once I can recall, and I don't remember what that</p> <p>19 conversation was about. It was several months</p> <p>20 later. It may have been just before we received 03:50</p> <p>21 the response or after. I really don't recall.</p> <p>22 But I know I spoke to him once after.</p> <p>23 Q. Do you think that conversation concerned</p> <p>24 the reply?</p>

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<p>129</p> <p>1 A. I really don't remember. 03:50</p> <p>2 Q. Other than your conversation with</p> <p>3 Dr. Verburg and your conversation with</p> <p>4 Dr. Silverstein, did you have any other</p> <p>5 conversations at any time regarding CLASS with any 03:50</p> <p>6 of these seventeen authors?</p> <p>7 A. No.</p> <p>8 Q. And other than your two manuscript</p> <p>9 meetings and your hallway interaction with</p> <p>10 Dr. Winker, did you do anything else regarding the 03:51</p> <p>11 CLASS publication?</p> <p>12 A. Yeah. I had to approve the final draft.</p> <p>13 I had to read it and I approved it.</p> <p>14 Q. Other than reading it, did you do</p> <p>15 anything else before approving it? 03:51</p> <p>16 A. Like what?</p> <p>17 Q. It's just my question. Did you do</p> <p>18 anything else?</p> <p>19 A. There's nothing else to be done, no.</p> <p>20 Q. I think you testified earlier, but 03:51</p> <p>21 you'll correct me if I'm wrong, that you never</p> <p>22 examined the underlying data of CLASS?</p> <p>23 A. No.</p> <p>24 Q. And that's true as of today; correct?</p>	<p>131</p> <p>1 conclusions from looking at the website; did you? 03:53</p> <p>2 A. I took away that there was more data and</p> <p>3 that when you looked at the data after twelve</p> <p>4 months or the forty-four, I believe it was</p> <p>5 forty-four incidences, and compared it with six 03:53</p> <p>6 months, when you looked at that other data there</p> <p>7 were no differences. And that was quite different</p> <p>8 than the differences reported in the study at six</p> <p>9 months.</p> <p>10 Q. Well, it's true, isn't it, that the 03:53</p> <p>11 manuscript reports that Celebrex did not meet its</p> <p>12 primary endpoint?</p> <p>13 A. Right.</p> <p>14 Q. That's disclosed in the manuscript;</p> <p>15 correct? 03:53</p> <p>16 A. Yes.</p> <p>17 Q. And that's true at the full study period</p> <p>18 as well; is that correct?</p> <p>19 A. It met the forty-four, they got</p> <p>20 ultimately forty-four bleeds and they wanted 03:54</p> <p>21 forty. Now, what other criteria, I don't know</p> <p>22 because I don't know what other endpoints they</p> <p>23 wanted.</p> <p>24 Q. Would you agree that the manuscript</p>
<p>130</p> <p>1 A. Yes. 03:52</p> <p>2 Q. Sitting here today, do you know what the</p> <p>3 results were of the trial at any given point in</p> <p>4 time?</p> <p>5 A. No. I only know what was shown on the 03:52</p> <p>6 FDA site and what was pointed out to me with</p> <p>7 reference in the letters that we published to</p> <p>8 which Dr. Silverstein and other authors responded.</p> <p>9 Q. What exactly did you see on the FDA</p> <p>10 website? 03:52</p> <p>11 A. Datapoints. Data that was, I don't</p> <p>12 recall exactly what was in there because I've seen</p> <p>13 a lot of stuff on that site for this particular</p> <p>14 study.</p> <p>15 All I know is once I saw it, I 03:52</p> <p>16 realized that the letters that we received, I went</p> <p>17 there to check to make sure they were accurate,</p> <p>18 that what they said was shown there as they</p> <p>19 reported.</p> <p>20 Q. So in other words, what you took away 03:53</p> <p>21 from it was that there was more data than six</p> <p>22 months; is that fair?</p> <p>23 A. Yes.</p> <p>24 Q. You didn't take away any other</p>	<p>132</p> <p>1 discloses that Celebrex did not demonstrate 03:54</p> <p>2 statistically significant superiority to the</p> <p>3 NSAIDs, to the comparators --</p> <p>4 MR. MONTGOMERY: Just to be clear, you</p> <p>5 mean Exhibit 3? 03:54</p> <p>6 MR. HALPER: Yes.</p> <p>7 BY MR. HALPER:</p> <p>8 Q. -- on the endpoint of ulcer</p> <p>9 complications?</p> <p>10 A. Let me just be clear. "In this study 03:54</p> <p>11 celecoxib at dosages greater than those indicated</p> <p>12 clinically was associated with a lower incidence</p> <p>13 of symptomatic ulcers and ulcer complications</p> <p>14 combined as well as other clinically important</p> <p>15 toxic effects compared with NSAIDs at standard 03:55</p> <p>16 dosages. The decrease in upper GI toxicity was</p> <p>17 strongest among patients not taking aspirin</p> <p>18 concomitantly."</p> <p>19 Now, that sounds like they're</p> <p>20 saying that this drug is better than the other 03:55</p> <p>21 drugs, the comparative drugs, at the endpoint</p> <p>22 which is GI bleeding. This is straight from the</p> <p>23 paper.</p> <p>24 Q. Do you understand that GI bleeding was</p>

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<p>133</p> <p>1 defined as an ulcer complication in the study? 03:55</p> <p>2 A. I know how it was defined, yes.</p> <p>3 Q. And that is different than a symptomatic</p> <p>4 ulcer?</p> <p>5 A. Yes. 03:56</p> <p>6 Q. And that there was an endpoint just of</p> <p>7 complicated ulcers; right?</p> <p>8 A. Right.</p> <p>9 Q. And an endpoint of combined symptomatic</p> <p>10 and complicated ulcers? 03:56</p> <p>11 A. Yes.</p> <p>12 Q. Do you have any reason to believe the</p> <p>13 statement is not accurate, that Celebrex was</p> <p>14 superior on the combined endpoint?</p> <p>15 A. Yes. 03:56</p> <p>16 Q. That's an accurate statement; isn't it?</p> <p>17 A. That's an accurate statement.</p> <p>18 And it's contrary to what you just</p> <p>19 asked me that you said it didn't show. It did</p> <p>20 show it. It's accurate. 03:56</p> <p>21 Q. I was just focusing on the complicated</p> <p>22 ulcer endpoint.</p> <p>23 A. Ah, but that's not what was reported.</p> <p>24 I'm just, I'm now an average clinician reading a</p>	<p>135</p> <p>1 A. I have an issue with being told that the 03:57</p> <p>2 study was a six-month study when it was not a</p> <p>3 six-month study.</p> <p>4 I have no issue with the findings</p> <p>5 as published. I already said that. If I had 03:58</p> <p>6 issue with these studies, this article would be</p> <p>7 pulled from the literature. I didn't do that. As</p> <p>8 here as stated with the follow-up letters to the</p> <p>9 editor, with the reply from the authors, it stands</p> <p>10 in the literature. 03:58</p> <p>11 At issue for me is that the CLASS</p> <p>12 study was not a six-month study as we were told</p> <p>13 repeatedly by at least Dr. Lefkowitz because he's</p> <p>14 the one that I saw what he wrote.</p> <p>15 Q. You didn't talk to Dr. Lefkowitz though? 03:58</p> <p>16 A. No. I saw what he wrote.</p> <p>17 Q. Before the publication?</p> <p>18 A. Yes.</p> <p>19 Q. And that was the communication with</p> <p>20 Dr. Winker; correct? 03:59</p> <p>21 A. Yes.</p> <p>22 Q. Okay. I understand your issue, but I</p> <p>23 just want to for the record understand what you</p> <p>24 did and didn't do to arrive at that conclusion,</p>
<p>134</p> <p>1 JAMA article that I trust and I read what I just 03:56</p> <p>2 read to you. That sure looks like a difference to</p> <p>3 me.</p> <p>4 Q. But in fact that difference is accurate</p> <p>5 based on the data? 03:57</p> <p>6 A. Yes, as analyzed.</p> <p>7 Q. As analyzed.</p> <p>8 Well, did you ever analyze whether</p> <p>9 for the full study period Celebrex was</p> <p>10 significantly superior on the combined endpoint? 03:57</p> <p>11 A. Did I?</p> <p>12 Q. Yes.</p> <p>13 A. I didn't have access to all the data.</p> <p>14 How would I do that?</p> <p>15 Q. Sitting here today, do you know whether 03:57</p> <p>16 Celebrex was significantly superior to the</p> <p>17 NSAIDs --</p> <p>18 A. No.</p> <p>19 Q. -- on a combined endpoint?</p> <p>20 A. No. 03:57</p> <p>21 Q. If it were superior to the NSAIDs for</p> <p>22 the full study period on the combined endpoint, do</p> <p>23 you have any issue then with that statement in</p> <p>24 here?</p>	<p>136</p> <p>1 and that's why I'm asking these questions. 03:59</p> <p>2 A. At the conclusion that -- which</p> <p>3 conclusion, sir? I'm sorry.</p> <p>4 Q. I understand what you just testified to.</p> <p>5 What I'm trying to get at by these questions is 03:59</p> <p>6 what you reviewed, what you looked at, who you</p> <p>7 spoke to, that led you to the belief you just</p> <p>8 testified to. So I'm not trying to shake you off</p> <p>9 that. I'm just trying to get at what you did and</p> <p>10 what you looked at. 03:59</p> <p>11 A. Right.</p> <p>12 Q. And what I understand from what you</p> <p>13 testified to is that before the publication you</p> <p>14 had the two manuscript meetings; correct?</p> <p>15 A. Yes. 04:00</p> <p>16 Q. You had the hallway conversations with</p> <p>17 Dr. Winker; correct?</p> <p>18 A. Yes. And I carefully read the paper.</p> <p>19 Q. After the publication you had a meeting</p> <p>20 with Dr. Verburg; correct? 04:00</p> <p>21 A. Oh, yes.</p> <p>22 Q. And a conversation with Dr. Silverstein;</p> <p>23 correct?</p> <p>24 A. Correct.</p>

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<p>137</p> <p>1 Q. And you -- 04:00</p> <p>2 A. I believe it was with Dr. Silverstein.</p> <p>3 Q. And you looked at the FDA website;</p> <p>4 correct?</p> <p>5 A. Yes. 04:00</p> <p>6 Q. Did you do anything else to gain an</p> <p>7 understanding of the CLASS study?</p> <p>8 A. Well, when you say in the beginning, you</p> <p>9 make it sound like I read it in the manuscript</p> <p>10 meeting, spend a half hour. We had reviewers who 04:00</p> <p>11 were peer reviewers who know this area, who know</p> <p>12 the area of research. They reviewed it. We had</p> <p>13 statistical reviewers. They reviewed it. I read</p> <p>14 those reports. The revised version contained</p> <p>15 recommended revisions from those experts. I read 04:01</p> <p>16 that and saw how closely those were followed.</p> <p>17 Now, after we published this study</p> <p>18 did I do any further analysis beyond what I said,</p> <p>19 I went to the site, verified that what those two</p> <p>20 letters were that we were going to publish were 04:01</p> <p>21 accurate, that's what I did. I published it, I</p> <p>22 met with two of the three people I had expected to</p> <p>23 meet, well, I expected to meet with two but the</p> <p>24 wrong two, and I published the explanation. What</p>	<p>139</p> <p>1 A. Uh-huh. I've got it. 04:03</p> <p>2 Q. If you look at the bottom of Page 2 to</p> <p>3 the top of Page 3, do you recall testifying about</p> <p>4 that statement earlier where it says "Suffice it</p> <p>5 to say, by the end of the meeting both editors 04:04</p> <p>6 expressed greater confidence in our motives and</p> <p>7 activities"?</p> <p>8 A. I'm sorry. Could you repeat that?</p> <p>9 Q. Do you recall testifying earlier about</p> <p>10 that statement? 04:04</p> <p>11 A. No. 6?</p> <p>12 Q. Right. But it really starts at the very</p> <p>13 bottom of Page 2 with "Suffice it to say."</p> <p>14 A. Oh, yes.</p> <p>15 Q. And I believe you testified in effect 04:04</p> <p>16 that Dr. Verburg appeared to believe that you had</p> <p>17 greater confidence in his motives; is that</p> <p>18 correct?</p> <p>19 A. Greater confidence in the motives and</p> <p>20 activities. 04:04</p> <p>21 Q. Right.</p> <p>22 A. Yes.</p> <p>23 Q. And you said in effect he may have</p> <p>24 believed that but it wasn't true. Do you recall</p>
<p>138</p> <p>1 we published stands in the literature. 04:02</p> <p>2 Q. Beyond what we've just talked about, you</p> <p>3 didn't do anything else in connection with CLASS;</p> <p>4 is that true?</p> <p>5 A. That's true. 04:02</p> <p>6 Q. How long did you spend looking at the</p> <p>7 FDA website?</p> <p>8 A. Oh, God, I don't know.</p> <p>9 Q. Approximately.</p> <p>10 A. Fifteen, twenty minutes, something like 04:02</p> <p>11 that. Enough time to verify that what those</p> <p>12 individuals wrote was based on what they said it</p> <p>13 was.</p> <p>14 Q. That there was more data than six</p> <p>15 months? 04:02</p> <p>16 A. Exactly.</p> <p>17 Q. Okay. If you pull out Exhibit 24, which</p> <p>18 was an August 23rd e-mail from Joy Dicker.</p> <p>19 MR. MONTGOMERY: 24 did you say?</p> <p>20 MR. HALPER: Yes. 04:03</p> <p>21 THE WITNESS: The August 23, 2001 e-mail</p> <p>22 from Joy Dicker?</p> <p>23 BY MR. HALPER:</p> <p>24 Q. Yes.</p>	<p>140</p> <p>1 that? 04:05</p> <p>2 A. I said he may have believed that. I</p> <p>3 don't agree with it. I had no greater confidence</p> <p>4 about the motives and activities.</p> <p>5 Q. So he was wrong, in your mind, when he 04:05</p> <p>6 was writing about your views and state of mind</p> <p>7 here; correct?</p> <p>8 A. He misinterpreted my politeness to be</p> <p>9 that I had confidence in the motives and in the</p> <p>10 activities. 04:05</p> <p>11 Q. Isn't it possible, Dr. DeAngelis, that</p> <p>12 the study authors here did not act with any intent</p> <p>13 to deceive anyone?</p> <p>14 A. Anything is possible. I'd like to</p> <p>15 believe that. 04:05</p> <p>16 Q. Well, the same way Dr. Verburg</p> <p>17 misinterpreted how you viewed things, is it</p> <p>18 possible that you have misinterpreted what the</p> <p>19 CLASS authors' state of mind and intent was in</p> <p>20 publishing the JAMA piece? 04:06</p> <p>21 MR. MONTGOMERY: Objection, calls for</p> <p>22 speculation.</p> <p>23 THE WITNESS: When we ask a</p> <p>24 straight-forward question in simple English to</p>



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<p style="text-align: right;">141</p> <p>1 very intelligent, accomplished individual, and the 04:06  2 response we get is not accurate, I can only, in my  3 mind it was not a misunderstanding of our  4 question, he understood perfectly well what we  5 were asking. 04:06  6 BY MR. HALPER:  7 Q. How do you know that?  8 A. May I get the, I'll show it to you, what  9 he said. I know that --  10 MR. NELSON: You understand it's in this 04:07  11 room. He knows exactly what you mean. He's going  12 to ask the questions.  13 THE WITNESS: How could he not  14 understand? My understanding from your answer is  15 that this study is complete at six months, and the 04:07  16 answer is your understanding is correct. What's  17 not to understand about that?  18 BY MR. HALPER:  19 Q. That was Dr. Lefkowitz's statement;  20 right? Correct? 04:07  21 A. Yes, right.  22 Q. No one ever told you that Dr. Lefkowitz  23 confessed to lying; correct?  24 A. Oh, no.</p>	<p style="text-align: right;">143</p> <p>1 Q. You don't have any reason to believe 04:09  2 that any of the other sixteen authors listed here  3 saw Dr. Lefkowitz's e-mail; do you?  4 A. No. But they signed the statement that  5 says that they agree that the corresponding author 04:09  6 will represent them. It's in the statement that  7 they sign. So I don't know if they saw it or not.  8 Q. Let me, just to make things go a little  9 quicker, my question was simply do you have any  10 reason to believe the other sixteen authors saw 04:09  11 Dr. Lefkowitz's correspondence with Dr. Winker?  12 A. I don't know.  13 Q. So you have no reason to believe they  14 did?  15 A. Or they didn't. 04:10  16 Q. Okay. And your basis for believing at  17 least that Dr. Lefkowitz was lying is these  18 e-mails; correct?  19 A. Malice? That's a tough word.  20 Q. I didn't say malice. 04:10  21 A. I'm sorry. I misheard you.  22 Q. That is a tough word.  23 A. Yes, please. I would not say that.  24 Q. Your basis for believing that</p>
<p style="text-align: right;">142</p> <p>1 Q. You don't have any contemporaneous 04:07  2 evidence other than how you read the e-mails that  3 Dr. Lefkowitz was intentionally deceiving anyone;  4 correct?  5 A. I have his word that he told us 04:08  6 something that was false. This was not a  7 six-month study.  8 Did he do it deliberately? I mean  9 did he, how can you, if I ask you is there water  10 in this bottle and you say no, there's no water in 04:08  11 that bottle? Now, either you're not very bright,  12 which is not the case with Dr. Lefkowitz, you're  13 blind, or you're lying.  14 Q. You never spoke to Dr. Lefkowitz;  15 correct? 04:08  16 A. No.  17 Q. And the e-mails came exclusively from  18 Dr. Lefkowitz, correct, that you're talking about?  19 A. The ones I'm talking about, yes.  20 Q. And they went to Dr. Winker; correct? 04:09  21 A. Yes. But I saw every one because when  22 people send things, everything comes under my name  23 because I'm ultimately responsible. So the  24 understanding is I will see everything.</p>	<p style="text-align: right;">144</p> <p>1 Dr. Lefkowitz lied is based on his e-mails. 04:10  2 A. E-mails, yes. That's better, yes.  3 Q. You don't have any basis other than the  4 e-mails for believing that the authors lied to  5 you; isn't that right? 04:10  6 A. What else do you need?  7 Q. Please.  8 A. No. There's nothing else.  9 Q. If those other sixteen authors never saw  10 those e-mails, then you have no basis to believe 04:11  11 they intentionally misled you; isn't that right?  12 A. They signed a statement that the  13 corresponding author represents, them and the  14 paper we have signed by every one of them gives,  15 it says the CLASS study, a randomized controlled 04:11  16 trial, and it reports six months data.  17 Q. You testified that your basis for  18 believing that Dr. Lefkowitz was lying was the  19 e-mail exchange with Dr. Winker; correct?  20 A. Yes. 04:11  21 Q. You had no other basis for concluding  22 that he lied; correct?  23 A. I need no others.  24 Q. But you have no others; correct?</p>

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<p>145</p> <p>1 A. I don't need any others. 04:12</p> <p>2 Q. But if there are more, I'd like to know</p> <p>3 about them.</p> <p>4 A. I don't know. No. There are none.</p> <p>5 Q. Okay. If the other sixteen authors -- 04:12</p> <p>6 let me withdraw that.</p> <p>7 You understand that when I talk</p> <p>8 about intent, state of mind, it means someone</p> <p>9 actually meant to do something. You understand</p> <p>10 that? 04:12</p> <p>11 A. I understand.</p> <p>12 Q. Okay. If the other sixteen authors</p> <p>13 never saw the e-mails that formed the basis for</p> <p>14 your belief that Dr. Lefkowitz lied, then you have</p> <p>15 no reason to believe that those sixteen people 04:12</p> <p>16 intended to deceive you; isn't that right?</p> <p>17 A. Only in that they gave me a paper that</p> <p>18 says it's the CLASS study and it is not the CLASS</p> <p>19 study.</p> <p>20 Q. But that is not what you testified that 04:12</p> <p>21 led you to believe that Dr. Lefkowitz had lied.</p> <p>22 In fact, you testified that the JAMA manuscript is</p> <p>23 accurate as printed.</p> <p>24 A. This is.</p>	<p>147</p> <p>1 A. No. 04:14</p> <p>2 Q. -- or the public?</p> <p>3 A. No.</p> <p>4 Q. Again, other than what you testified to,</p> <p>5 meaning Lefkowitz's e-mails and, well, other than 04:15</p> <p>6 Lefkowitz's e-mails and the study, do you have any</p> <p>7 reason to believe that Cyril intended to deceive</p> <p>8 anyone?</p> <p>9 A. Cyril?</p> <p>10 Q. Cyril. Do you understand that at the 04:15</p> <p>11 time of the CLASS trial Cyril was the corporate</p> <p>12 sponsor?</p> <p>13 A. Oh, C-Y-R-I-L. I'm thinking Cyril who?</p> <p>14 I'm sorry. No, I don't.</p> <p>15 Q. Other than what you testified to, do you 04:16</p> <p>16 have any reason to believe that Pharmacia intended</p> <p>17 to deceive anyone?</p> <p>18 A. No.</p> <p>19 Q. Other than what you testified to, do you</p> <p>20 have any reason to believe that Pfizer intended to 04:16</p> <p>21 deceive anyone?</p> <p>22 A. Pfizer wasn't even there at the time;</p> <p>23 were they?</p> <p>24 Q. I take it that's a No?</p>
<p>146</p> <p>1 Q. Right. 04:13</p> <p>2 A. The six-month data are accurate as</p> <p>3 published.</p> <p>4 Q. Right.</p> <p>5 A. This is not the CLASS study. And when 04:13</p> <p>6 the representative of this group tells me through</p> <p>7 an e-mail to Dr. Winker that this is a six-month</p> <p>8 study, that's a lie.</p> <p>9 Q. Other than the fact that you believe</p> <p>10 Dr. Lefkowitz represented the other authors, do 04:13</p> <p>11 you have any reason to attribute his statement to</p> <p>12 them?</p> <p>13 A. They signed this. This is a six-month</p> <p>14 study. It says the CLASS study, a randomized</p> <p>15 controlled trial. They signed their names to 04:14</p> <p>16 this.</p> <p>17 This is not the CLASS study. This</p> <p>18 is a portion of the CLASS study. And the CLASS</p> <p>19 study did not stop at six months. And they are</p> <p>20 authors. 04:14</p> <p>21 Q. Other than Dr. Lefkowitz's e-mail and</p> <p>22 the fact that all seventeen authors signed the</p> <p>23 study, do you have any reason to believe that any</p> <p>24 of those people intended to deceive you --</p>	<p>148</p> <p>1 A. That's a No. 04:16</p> <p>2 Q. Okay. If you turn to Exhibit 22, it's a</p> <p>3 May 22nd e-mail from Mona Wahba.</p> <p>4 Did you ever see this e-mail before</p> <p>5 today? 04:17</p> <p>6 A. No.</p> <p>7 Q. Do you know who Mona Wahba is?</p> <p>8 A. No.</p> <p>9 Q. Do you know what company she works for?</p> <p>10 A. No. 04:17</p> <p>11 Q. Do you know what position she holds?</p> <p>12 A. No.</p> <p>13 Q. Do you know what, if any, involvement</p> <p>14 she had in the CLASS study?</p> <p>15 A. No. 04:17</p> <p>16 MR. NELSON: Excuse me a second. Some</p> <p>17 of that, the answers to some of your questions are</p> <p>18 on this document.</p> <p>19 MR. HALPER: Well, but I don't think</p> <p>20 Dr. DeAngelis has an independent recollection. 04:17</p> <p>21 MR. NELSON: No, no. As long as you</p> <p>22 make it clear other than what she may read on this</p> <p>23 document.</p> <p>24 THE WITNESS: No. You said before I saw</p>

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<p>149</p> <p>1 this document. 04:17</p> <p>2 MR. NELSON: Oh, okay. I'm sorry for</p> <p>3 interrupting.</p> <p>4 BY MR. HALPER:</p> <p>5 Q. As far as you know, Dr. Wahba, well, she 04:17</p> <p>6 is not in fact one of the authors of the study;</p> <p>7 correct?</p> <p>8 A. That I know.</p> <p>9 Q. She didn't correspond with JAMA</p> <p>10 concerning the study; correct? 04:18</p> <p>11 A. No.</p> <p>12 Q. Do you recall you were asked earlier if</p> <p>13 you were ever told that the authors were</p> <p>14 cherry-picking the data? Do you recall that</p> <p>15 question? 04:18</p> <p>16 A. Yes.</p> <p>17 Q. And you said you were never told that.</p> <p>18 Do you recall that?</p> <p>19 A. I recall that, yes.</p> <p>20 Q. That phrase appears in Mona Wahba's 04:18</p> <p>21 e-mail; correct?</p> <p>22 A. Correct.</p> <p>23 Q. Isn't it possible that you were never</p> <p>24 told that the authors were cherry-picking the data</p>	<p>151</p> <p>1 A. Yes. 04:19</p> <p>2 Q. You were asked -- well, before I get</p> <p>3 into that, do you know who Emilio Arbe is?</p> <p>4 A. No.</p> <p>5 Q. Have you ever heard of him before? 04:19</p> <p>6 A. No.</p> <p>7 Q. Do you know what company he worked for</p> <p>8 at the time?</p> <p>9 A. No.</p> <p>10 Q. Do you know what position he had at the 04:20</p> <p>11 time?</p> <p>12 A. No.</p> <p>13 Q. Do you know if he had any involvement in</p> <p>14 the CLASS study?</p> <p>15 A. No. 04:20</p> <p>16 Q. You were asked if it is proper</p> <p>17 scientific behavior to do what Emilio Arbe alleges</p> <p>18 was done here. Do you recall that?</p> <p>19 A. Yes.</p> <p>20 Q. And you said it was not. Do you recall 04:20</p> <p>21 that?</p> <p>22 A. That's true.</p> <p>23 Q. Do you have any reason to believe that</p> <p>24 Emilio Arbe in fact knows what was done with the</p>
<p>150</p> <p>1 because in fact in their minds they were not 04:18</p> <p>2 cherry-picking the data?</p> <p>3 A. Yes.</p> <p>4 Q. That is possible.</p> <p>5 A. That's possible. 04:18</p> <p>6 Q. If you turn to Exhibit 28, it's an</p> <p>7 e-mail chain. It starts with the September 8th</p> <p>8 e-mail from Lefkowitz.</p> <p>9 A. Okay.</p> <p>10 Q. You were asked about a statement on the 04:19</p> <p>11 third page of this chain. It's the third</p> <p>12 paragraph in the Emilio Arbe e-mail. Do you see</p> <p>13 that?</p> <p>14 A. I see it.</p> <p>15 Q. Do you recall you were asked about the 04:19</p> <p>16 third paragraph in the e-mail?</p> <p>17 A. "With a bit of data massage," that one?</p> <p>18 Q. Yes. It says "With a bit of data</p> <p>19 massage, what Steve Geis and his team have done is</p> <p>20 to focus on the six-month data for no other reason 04:19</p> <p>21 that it happens to look better," and then it goes</p> <p>22 on.</p> <p>23 Do you recall being asked about</p> <p>24 that?</p>	<p>152</p> <p>1 data? 04:20</p> <p>2 A. I have no idea. Obviously he knew a</p> <p>3 fair amount about the data going into this, but I</p> <p>4 don't know what happened after.</p> <p>5 Q. The fact that it is not generally proper 04:20</p> <p>6 scientific behavior to do what Emilio Arbe charges</p> <p>7 does not mean that in fact that's what was done</p> <p>8 here; isn't that true?</p> <p>9 A. That's correct.</p> <p>10 Q. Okay. If you turn to Exhibit 27, which 04:20</p> <p>11 is a March 20th e-mail from Carolyn Wilson. You</p> <p>12 were asked about a statement, the second to last</p> <p>13 page in the e-mail, 816.</p> <p>14 A. Uh-huh.</p> <p>15 Q. It's the bullet point under Option 1 and 04:21</p> <p>16 then under Trial Design Issues, the third bullet</p> <p>17 point under that, Worst Case. Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. It says "we have to attack the trial</p> <p>20 design if we do not see the results we want." Do 04:22</p> <p>21 you see that?</p> <p>22 A. Yes.</p> <p>23 Q. And you were asked I believe if that is</p> <p>24 proper and you testified no. Do you remember</p>

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<p>153</p> <p>1 that? 04:22</p> <p>2 A. That's correct.</p> <p>3 Q. Do you know who authored this document?</p> <p>4 A. Rich Montwill? Oh, I only know by</p> <p>5 reading. Do I know who this person is? Carolyn 04:22</p> <p>6 Wilson? I don't know Carolyn Wilson.</p> <p>7 Q. Had you ever heard of her before today?</p> <p>8 A. No.</p> <p>9 Q. Do you know what involvement she had in</p> <p>10 the CLASS? 04:22</p> <p>11 A. No.</p> <p>12 Q. Do you have any idea if anyone actually</p> <p>13 did what she is suggesting be done here?</p> <p>14 A. No.</p> <p>15 Q. You don't know? 04:22</p> <p>16 A. I don't know.</p> <p>17 Q. Do you recall you were asked a number of</p> <p>18 questions about informative censoring?</p> <p>19 A. Yes.</p> <p>20 Q. Have you ever heard that concept 04:23</p> <p>21 referred to as withdrawal of susceptibles?</p> <p>22 A. Not in those words but in that meaning,</p> <p>23 yes.</p> <p>24 Q. If you look at Exhibit 31, which is</p>	<p>155</p> <p>1 My problem is this decision was 04:25</p> <p>2 made by the authors, I assume, without telling us.</p> <p>3 And rather than telling us the truth of why they</p> <p>4 chose six months, they told us the study was six</p> <p>5 months. 04:26</p> <p>6 Q. Understood. But you're not saying that</p> <p>7 Dr. Silverstein is wrong in his view of the post</p> <p>8 six-month data?</p> <p>9 A. No, he's not.</p> <p>10 Q. In fact, the data after six months could 04:26</p> <p>11 be confounded; isn't that right?</p> <p>12 A. It could be.</p> <p>13 Q. And if the data after six months are</p> <p>14 confounded, doesn't that mean that that data</p> <p>15 doesn't tell us anything about the safety of the 04:26</p> <p>16 drug?</p> <p>17 A. If it were presented in the full twelve</p> <p>18 months with full explanation of why things changed</p> <p>19 after six months, then the reader could make the</p> <p>20 decision whether they think that Celebrex is I'll 04:26</p> <p>21 use the word "better than," as far as GI bleeding</p> <p>22 goes, than aspirin and NSAIDs. They didn't do</p> <p>23 that.</p> <p>24 Q. Agreed. They didn't do that.</p>
<p>154</p> <p>1 Dr. Silverstein's reply, I'm again going to focus 04:23</p> <p>2 on his reply.</p> <p>3 In this document is it accurate to</p> <p>4 say that Dr. Silverstein was explaining why the</p> <p>5 authors used the six-month dataset? 04:24</p> <p>6 A. Yes.</p> <p>7 Q. Do you have any basis to argue with</p> <p>8 whether the six-month data is a valid dataset?</p> <p>9 A. No. That's why I allowed this to be</p> <p>10 published and why I say the article, the editorial 04:24</p> <p>11 and this stands and have not been pulled.</p> <p>12 Q. He writes in the second paragraph,</p> <p>13 second sentence, "We submitted only this</p> <p>14 information because the authors believed the</p> <p>15 six-month data were the most scientifically and 04:25</p> <p>16 clinically valid. Data after six months were so</p> <p>17 confounded as to be difficult to interpret for</p> <p>18 assessing a drug-related causal GI toxicity." Do</p> <p>19 you see that?</p> <p>20 A. Yes. 04:25</p> <p>21 Q. Do you have any basis to disagree with</p> <p>22 those statements?</p> <p>23 A. I have no basis to disagree with those</p> <p>24 statements.</p>	<p>156</p> <p>1 My question though is a little 04:27</p> <p>2 different, okay. If the data after six months is</p> <p>3 confounded or statistically invalid, then doesn't</p> <p>4 that mean that that data is not instructive</p> <p>5 regarding the safety or efficacy of the drug? 04:27</p> <p>6 A. If I had the opportunity --</p> <p>7 MR. MONTGOMERY: Objection, calls for</p> <p>8 speculation. I apologize.</p> <p>9 THE WITNESS: If I or I with a</p> <p>10 bio-statistician sat there, saw all the data, and 04:27</p> <p>11 said oh, this is what happened, and I made the</p> <p>12 decision, not them, perhaps they're right, perhaps</p> <p>13 they're not.</p> <p>14 The issue is they don't give you</p> <p>15 the data, they just give an explanation, and we 04:28</p> <p>16 left it at that.</p> <p>17 BY MR. HALPER:</p> <p>18 Q. But as you just said, they saw the data;</p> <p>19 correct?</p> <p>20 A. I assume so. 04:28</p> <p>21 Q. So I'm asking you, I'm freely</p> <p>22 acknowledging you to assume that the data after</p> <p>23 six months in fact is confounded and statistically</p> <p>24 suspect. Okay?</p>

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<p>157</p> <p>1 A. I don't know that. 04:28</p> <p>2 Q. I'm not saying you know it. I'm saying</p> <p>3 assume that Dr. Silverstein is right for a moment.</p> <p>4 A. Okay.</p> <p>5 Q. If Dr. Silverstein is right, then the 04:28</p> <p>6 post six-month data are not instructive regarding</p> <p>7 the efficacy or safety of the drug; isn't that</p> <p>8 true?</p> <p>9 MR. MONTGOMERY: Objection to form,</p> <p>10 improper hypothetical. 04:29</p> <p>11 THE WITNESS: The issue is we put our</p> <p>12 reputation and our readers believe and trust in us</p> <p>13 that we were publishing the CLASS study, and</p> <p>14 that's not what we were given. And I have no</p> <p>15 reason one way or the other to know that this is 04:29</p> <p>16 not just made-up stuff. I don't know.</p> <p>17 What I do know, what I do know, is</p> <p>18 that the data as of six months, the way it was</p> <p>19 analyzed, is accurate, but it's not the CLASS</p> <p>20 study. And after that I don't know. 04:30</p> <p>21 I've been told by some people who</p> <p>22 have analyzed it that it shows very clearly that</p> <p>23 you really shouldn't have used the first six</p> <p>24 months, and there's arguments, and I understand</p>	<p>159</p> <p>1 MR. MONTGOMERY: Object to form. 04:31</p> <p>2 THE WITNESS: If indeed that's true and</p> <p>3 the people have the opportunity to see it and to</p> <p>4 say it's confounded and agree, then he's right.</p> <p>5 But to take his word for it without seeing the 04:32</p> <p>6 data takes a leap of faith that I'm not willing to</p> <p>7 give.</p> <p>8 BY MR. HALPER:</p> <p>9 Q. Understood, you're not. But if he's</p> <p>10 right and someone is assessing simply the efficacy 04:32</p> <p>11 or safety of this drug, if he's right, the post</p> <p>12 six-month data are not going to help; isn't that</p> <p>13 true?</p> <p>14 MR. MONTGOMERY: Object to form.</p> <p>15 THE WITNESS: That's true. 04:32</p> <p>16 But to use this study, to come up</p> <p>17 with those conclusions that people will read and</p> <p>18 believe is the CLASS study, is not right because</p> <p>19 it's not the CLASS study. And I don't know if the</p> <p>20 second six months if they're right or not. 04:32</p> <p>21 BY MR. HALPER:</p> <p>22 Q. I understand that you don't know. I'm</p> <p>23 not suggesting you do. I'm only, and you've</p> <p>24 answered me, but I just want to clarify it, I</p>
<p>158</p> <p>1 that. But the problem is this is not the CLASS 04:30</p> <p>2 study.</p> <p>3 BY MR. HALPER:</p> <p>4 Q. That is your problem; correct?</p> <p>5 A. That's my problem. 04:30</p> <p>6 Q. You understand I'm here because I have a</p> <p>7 different problem; correct?</p> <p>8 A. I think you've got a lot of problems,</p> <p>9 God bless you. Go ahead.</p> <p>10 Q. So I hear what you're saying. Okay? 04:30</p> <p>11 A. Yes.</p> <p>12 MR. NELSON: He hears your pain.</p> <p>13 BY MR. HALPER:</p> <p>14 Q. You've said that informative,</p> <p>15 Dr. Silverstein -- let me withdraw that. 04:31</p> <p>16 You've testified that you have no</p> <p>17 reason to conclude that Dr. Silverstein is wrong</p> <p>18 regarding his informative censoring view; correct?</p> <p>19 A. That's right.</p> <p>20 Q. Knowing your problem, assume he's right. 04:31</p> <p>21 Doesn't that say if the data after six months is</p> <p>22 confounded and statistically suspect, then isn't</p> <p>23 that data, it doesn't instruct anybody regarding</p> <p>24 efficacy or safety of the drug; isn't that true?</p>	<p>160</p> <p>1 believe your answer was it is true that if he is 04:33</p> <p>2 right then the post six-month data do not instruct</p> <p>3 us on the efficacy or the safety of the drug;</p> <p>4 correct?</p> <p>5 MR. MONTGOMERY: Object to form. 04:33</p> <p>6 THE WITNESS: It's true, but it is wrong</p> <p>7 to allow the first six months data to be published</p> <p>8 in a journal like JAMA with those results without</p> <p>9 also explaining why the second six months data</p> <p>10 were not published. And he says it, in retrospect 04:33</p> <p>11 we acknowledge that we could have avoided</p> <p>12 confusion, et cetera, et cetera, et cetera.</p> <p>13 Avoided confusion. So he says there's confusion</p> <p>14 about the CLASS study, supposed CLASS study, that</p> <p>15 was published in JAMA. 04:34</p> <p>16 THE VIDEOGRAPHER: This concludes</p> <p>17 Videotape No. 4. The time now is approximately</p> <p>18 4:34 p.m. The deposition will continue on</p> <p>19 Videotape No. 5.</p> <p>20 (WHEREUPON a recess was taken.) 04:34</p> <p>21 THE VIDEOGRAPHER: This will begin</p> <p>22 Videotape No. 5 of the deposition of Catherine</p> <p>23 DeAngelis taken in the matter of Case No. 03-1519</p> <p>24 on the 12th day of January, 2007. The time now is</p>

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<p>161</p> <p>1 approximately 4:40 p.m., and I'll remind the 04:40</p> <p>2 witness once more that she's under oath.</p> <p>3 THE WITNESS: Allow me to clarify what</p> <p>4 I'm trying to say.</p> <p>5 BY MR. HALPER: 04:40</p> <p>6 Q. Sure.</p> <p>7 A. If a study is designed for a certain</p> <p>8 point, all the data gathered until you reach that</p> <p>9 point are valuable and all of it should be</p> <p>10 analyzed and you can say, all right, at six months 04:40</p> <p>11 it looks this way but at twelve months it looks</p> <p>12 this way. So if you only had six months data and</p> <p>13 that was your decided endpoint, then it's</p> <p>14 absolutely legitimate for you to say well, yeah,</p> <p>15 we follow them thereafter because of whatever, 04:41</p> <p>16 post hoc whatever, but our study was six months,</p> <p>17 that's one story.</p> <p>18 My point is that this was a study</p> <p>19 endpoint forty bleeds. It took twelve months</p> <p>20 essentially to reach that, and therefore, all 04:41</p> <p>21 twelve months data are valid, not just six months.</p> <p>22 Even though you say hey, look, the first six</p> <p>23 months because we got patients following them all</p> <p>24 along until we get forty bleeds and we didn't get</p>	<p>163</p> <p>1 wouldn't have published them if you disagreed with 04:43</p> <p>2 them; correct?</p> <p>3 A. Right.</p> <p>4 Q. Or if you believed he was being</p> <p>5 deceitful; correct? 04:43</p> <p>6 A. In the reply?</p> <p>7 Q. Yes.</p> <p>8 A. No. I wouldn't have published.</p> <p>9 Q. If you thought he was being deceitful in</p> <p>10 the reply, you would not have published the reply; 04:43</p> <p>11 correct?</p> <p>12 A. That's true.</p> <p>13 Q. You didn't ask him I assume when you</p> <p>14 spoke to him are you being deceitful?</p> <p>15 A. No, of course not. 04:43</p> <p>16 Q. And you accepted the reply for</p> <p>17 publication; correct?</p> <p>18 A. Correct.</p> <p>19 Q. I just want to clarify something. You</p> <p>20 were asked a number of questions earlier by 04:44</p> <p>21 Mr. Montgomery to give your opinions on various</p> <p>22 subjects. Do you recall that?</p> <p>23 A. Oh, yes.</p> <p>24 Q. Generally.</p>
<p>162</p> <p>1 the forty bleeds until here, but over here when we 04:41</p> <p>2 only had twenty-two bleeds, I don't know how many,</p> <p>3 okay, this is what we found, and this stuff we</p> <p>4 found less because yada, yada, yada. That's not</p> <p>5 valid. 04:42</p> <p>6 It's valid only that you report to</p> <p>7 what you said was your endpoint. And that's why</p> <p>8 the six-month data, malice or deliberate or not,</p> <p>9 six months data in the CLASS study doesn't do it,</p> <p>10 you have to report all twelve. You can then 04:42</p> <p>11 analyze it and say we dropped out the last six</p> <p>12 months because yada, yada, yada, and then the</p> <p>13 reader can decide. But you must report all the</p> <p>14 data, and that's not what this study did.</p> <p>15 Q. And I understand that's your problem 04:42</p> <p>16 with the study, and I appreciate the</p> <p>17 clarification.</p> <p>18 You, if I understand correctly, do</p> <p>19 not disagree, you have no reason to disagree, with</p> <p>20 any of the statements made in Dr. Silverstein's 04:43</p> <p>21 reply?</p> <p>22 A. No. I don't disagree. I don't have any</p> <p>23 problem. I published them.</p> <p>24 Q. Right, you published them. And you</p>	<p>164</p> <p>1 A. Generally, yeah. 04:44</p> <p>2 Q. You are an M.D.; correct?</p> <p>3 A. Correct.</p> <p>4 Q. Do you hold yourself out as an expert in</p> <p>5 statistics? 04:44</p> <p>6 A. No.</p> <p>7 Q. Do you hold yourself out as an expert in</p> <p>8 gastroenterology?</p> <p>9 A. Not in gastroenterology per se, no.</p> <p>10 Q. Do you hold yourself out as an expert on 04:44</p> <p>11 the data underlying the CLASS study?</p> <p>12 A. Without having seen it, no.</p> <p>13 Q. The views you're giving today are in</p> <p>14 your role as an editor of a publication; correct?</p> <p>15 A. Correct, and as a practicing physician. 04:45</p> <p>16 Q. But not as an expert; correct?</p> <p>17 MR. MONTGOMERY: Object, calls for a</p> <p>18 conclusion.</p> <p>19 THE WITNESS: Not in those three</p> <p>20 areas -- 04:45</p> <p>21 BY MR. HALPER:</p> <p>22 Q. Not in those three areas?</p> <p>23 A. Not in those three areas that you said.</p> <p>24 However, in the statistical area I</p>

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<p>165</p> <p>1 am not an expert but I have two statistical 04:45 2 bio-statisticians on my staff who are editors, and 3 we pay about another twenty for their statistical 4 analysis expertise. I am not a bio-statistician, 5 absolutely not. 04:45 6 Q. Did any of the statisticians on your 7 staff communicate with you regarding the 8 publication of the CLASS study? 9 A. They had to have approved it or we would 10 never have. 04:46 11 Q. Did you ever discuss with them the 12 informative censoring argument? 13 A. Not per se, no. 14 Q. What do you mean "not per se"? 15 A. Well, because that came up later in the 04:46 16 reply, not to the publication that they had 17 reviewed. 18 Q. And when it came up in the reply, did 19 you discuss it with your statisticians? 20 A. No. 04:46 21 Q. So while you have statisticians on your 22 staff, you did not discuss the informative 23 censoring issue with them in connection with the 24 CLASS?</p>	<p>167</p> <p>1 A. No. 04:47 2 Q. Or regarding rheumatology. 3 A. No. 4 Q. Or regarding CLASS. 5 A. No, certainly no. 04:47 6 Q. Okay. Thank you. 7 You talked earlier or referred 8 earlier to my problem and your problem. But you 9 understand that we're here today in connection 10 with a securities litigation? 04:48 11 A. Correct. 12 Q. Have you read any of the documents filed 13 with the court in that litigation? 14 A. No. 15 Q. Do you have any understanding of what 04:48 16 the case is about? 17 A. In general, yes. 18 Q. Do you understand that the plaintiffs 19 here are claiming that the price of Pharmacia 20 stock was artificially high because of the JAMA 04:48 21 publication? 22 A. The claim? Yes. I understand that. 23 Q. That's the claim. Do you understand 24 that?</p>
<p>166</p> <p>1 A. Not in relation to the CLASS study, 04:46 2 correct. 3 Q. Just a few more on the same topic. 4 Do you hold yourself out as an 5 expert in rheumatology? 04:46 6 MR. MONTGOMERY: Object to form. 7 THE WITNESS: No. 8 BY MR. HALPER: 9 Q. Do you hold yourself out as an expert in 10 arthritis drugs? 04:47 11 MR. MONTGOMERY: Object to form. 12 THE WITNESS: Arthritis drugs, no. A 13 pharmacologist? No. I'm not a pharmacologist. 14 BY MR. HALPER: 15 Q. How about as an expert in COX-2? 04:47 16 MR. MONTGOMERY: Object to form. 17 THE WITNESS: What do you mean by, 18 that's a pharmacologist. I'm not a 19 pharmacologist. 20 BY MR. HALPER: 04:47 21 Q. You wouldn't try and testify as an 22 expert regarding COX-2. 23 A. No. 24 Q. Or regarding arthritis drugs generally.</p>	<p>168</p> <p>1 A. Yes. 04:48 2 Q. Do you have any reason to believe that 3 the price of Pharmacia stock rose based on the 4 JAMA publication? 5 A. I've seen it before. 04:48 6 Q. Do you have any reason to believe it 7 happened here? 8 A. I have no reason to believe it didn't. 9 When JAMA publishes something about a drug, we see 10 this blip and I scratch my head. And I wondered 04:49 11 about this, and I found that most pharmaceutical 12 companies actually subscribe to JAMA, as they do 13 to the other big journals, and they watch, as do 14 lots of people in business. 15 So if they see something in a 04:49 16 journal like JAMA that says something good about a 17 product, they tend to believe it's true. 18 Q. Your testimony just now was based on 19 your general observations; correct? 20 A. General observations. Not to this case. 04:49 21 I have no idea about this case. 22 Q. You've never been an investment 23 professional -- 24 A. Absolutely, believe me. I've never</p>



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<p>169</p> <p>1 owned stock in my life. 04:49</p> <p>2 Q. And you're not an expert in the stock</p> <p>3 markets; correct?</p> <p>4 A. No.</p> <p>5 Q. Do you know what happened to the price 04:50</p> <p>6 of Pharmacia stock when the JAMA article was</p> <p>7 published?</p> <p>8 A. No.</p> <p>9 Q. And I take it, therefore, you don't know</p> <p>10 what effect, if any, the publication had on the 04:50</p> <p>11 price of the Pharmacia stock?</p> <p>12 A. I don't follow the stock market. I</p> <p>13 don't know.</p> <p>14 Q. And you would have no basis for an</p> <p>15 opinion about the impact of the article on the 04:50</p> <p>16 price of Pharmacia stock; correct?</p> <p>17 A. In this case, no.</p> <p>18 Q. Do you have any reason to believe -- let</p> <p>19 me withdraw that.</p> <p>20 Do you know of anyone who purchased 04:50</p> <p>21 or sold Pharmacia stock on the basis of the JAMA</p> <p>22 publication?</p> <p>23 A. No.</p> <p>24 Q. Given that, do you have any reason to</p>	<p>171</p> <p>1 A. Yes. 04:52</p> <p>2 Q. You have no reason to believe that the</p> <p>3 distribution of reprints affected the price of</p> <p>4 Pharmacia stock; do you?</p> <p>5 A. I wouldn't know, no. 04:52</p> <p>6 Q. You have no reason to believe that</p> <p>7 anyone purchased or sold Pharmacia stock based on</p> <p>8 a reprint of the publication; isn't that right?</p> <p>9 A. That's correct.</p> <p>10 Q. You testified earlier that soon after 04:53</p> <p>11 the advisory committee hearings in February of</p> <p>12 2001 you went and looked at the FDA website;</p> <p>13 correct?</p> <p>14 A. Yes.</p> <p>15 Q. And information was posted there; 04:53</p> <p>16 correct?</p> <p>17 A. Correct.</p> <p>18 Q. Were those FDA reviewer reports that</p> <p>19 were published there?</p> <p>20 A. Gee, I don't remember. I really don't 04:53</p> <p>21 remember.</p> <p>22 Q. But as of February of 2001, the full</p> <p>23 data was available on the FDA website; isn't that</p> <p>24 true?</p>
<p>170</p> <p>1 believe people did or did not purchase Pharmacia 04:50</p> <p>2 stock on the basis of the JAMA publication?</p> <p>3 A. I have no reason, I have no knowledge.</p> <p>4 Q. If you turn to Exhibit 32, which is the</p> <p>5 Juni article. 04:51</p> <p>6 A. 32?</p> <p>7 Q. It's the BMJ article by Peter Juni.</p> <p>8 MR. NELSON: Do you want mine?</p> <p>9 THE WITNESS: Do you have yours? That</p> <p>10 will work. Yes. 04:52</p> <p>11 BY MR. HALPER:</p> <p>12 Q. You just testified you have no basis to</p> <p>13 know whether or not whether the price of Pharmacia</p> <p>14 stock was influenced by the JAMA publication;</p> <p>15 correct? 04:52</p> <p>16 A. That's correct.</p> <p>17 Q. Do you see on the second page of Exhibit</p> <p>18 32, the first full paragraph there's a "Firstly"</p> <p>19 and a "Secondly"?</p> <p>20 A. Yes. 04:52</p> <p>21 Q. It says "Secondly, the flawed findings</p> <p>22 published in the original article appear to be</p> <p>23 widely distributed and believed." Do you see</p> <p>24 that?</p>	<p>172</p> <p>1 A. As I recall, yes. I believe they were 04:53</p> <p>2 full.</p> <p>3 Q. So isn't it also true that as of</p> <p>4 February of 2001 it was public that this was more</p> <p>5 than a six-month study? 04:54</p> <p>6 A. If people went to the site, they could</p> <p>7 see it.</p> <p>8 Q. And that's publicly available; correct?</p> <p>9 MR. MONTGOMERY: Object to form.</p> <p>10 THE WITNESS: Yes. 04:54</p> <p>11 BY MR. HALPER:</p> <p>12 Q. Had you seen the Juni article before</p> <p>13 today?</p> <p>14 A. I'm sorry?</p> <p>15 Q. Exhibit 32. 04:54</p> <p>16 A. BMJ?</p> <p>17 Q. Yes, had you seen that before today?</p> <p>18 A. You know, I'm looking at it. I think I</p> <p>19 saw it. There were a lot of things published. I</p> <p>20 may have seen it. It didn't surprise me. So I 04:54</p> <p>21 probably read it. I read a lot.</p> <p>22 Q. You don't have a specific recollection</p> <p>23 though?</p> <p>24 A. No.</p>

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<p>173</p> <p>1 Q. Is it fair to say that the first time 04:54 2 you examined it in substance was today? 3 A. Yes. 4 Q. And, therefore, is it also true that you 5 have no basis to testify whether there is anything 04:55 6 in the Juni article that is different from what is 7 publicly available or was publicly available on 8 the FDA website as of February 2001? 9 MR. MONTGOMERY: Object to form. 10 THE WITNESS: You mean is there anything 04:55 11 in here? 12 BY MR. HALPER: 13 Q. That's not public. 14 MR. MONTGOMERY: Object to form. 15 THE WITNESS: I saw it, so it must have 04:55 16 been, it was publicly available, yeah. 17 BY MR. HALPER: 18 Q. Do you know whether there is anything in 19 the Juni article that was not publicly available 20 from the FDA website in February '01? 04:55 21 A. Well, the idea about the -- 22 MR. MONTGOMERY: Object to form. 23 THE WITNESS: -- the thirty thousand 24 reprints, I didn't even know that until now.</p>	<p>175</p> <p>1 Dr. Lefkowitz and Dr. Winker. Do you recall that? 05:02 2 A. Yes. 3 Q. Do you know whether Dr. Lefkowitz 4 forwarded or communicated his e-mail exchanges 5 with Dr. Winker to anyone else? 05:02 6 A. No. 7 Q. You don't know? 8 A. I don't know. 9 MR. HALPER: No questions at this time, 10 no further questions. 05:02 11 MR. NELSON: Neither of you? 12 MR. HALPER: No, no, no. Do you have 13 some more? 14 MR. MONTGOMERY: Yes, but very, very 15 short, although that's the classic. 05:02 16 17 18 19 20 21 22 23 24</p>
<p>174</p> <p>1 BY MR. HALPER: 04:55 2 Q. Anything else? 3 A. I don't know about the sales. That 4 wasn't on the FDA site, the amount of sales. 5 Q. If you read to yourself the "Firstly," 04:56 6 the few sentences in the Juni article, then my 7 question will be do you know whether anything 8 under "Firstly" was not already on the FDA 9 website. 10 MR. MONTGOMERY: Object to form. 04:56 11 THE WITNESS: I believe all that was on 12 the website. People could have accessed that and 13 analyzed it if they wanted to. 14 MR. HALPER: Let me take two minutes. I 15 may be done, but let me just check. 04:56 16 THE VIDEOGRAPHER: Going off the record 17 at 4:56 p.m. 18 (WHEREUPON a recess was taken.) 19 THE VIDEOGRAPHER: And we are back on 20 the record. The time now is approximately 05:02 21 5:02 p.m. 22 BY MR. HALPER: 23 Q. Dr. DeAngelis, earlier we were 24 discussing a bit the e-mail exchanges between</p>	<p>176</p> <p>1 FURTHER EXAMINATION 05:03 2 BY MR. MONTGOMERY: 3 BY MR. MONTGOMERY: 4 Q. Do you have Exhibit 31? It's the reply 5 letter. 05:03 6 A. Here it is. This is it. 7 Q. Please look at the second page. And I 8 want to ask you about that, the paragraph that 9 begins on the bottom of the left column and 10 continues to the top of the right one, it starts 05:03 11 "The problem after six months." 12 A. Yes. 13 Q. Do you recall earlier we talked about 14 the phrase "attacking the trial design"? 15 A. The -- 05:04 16 Q. "Attacking the trial design." 17 A. Yes. 18 Q. Do you think that that paragraph that I 19 just identified could be characterized as 20 attacking the trial design of CLASS? 05:04 21 MR. HALPER: Objection to form, 22 speculation, vague. By who? 23 THE WITNESS: Without knowing exactly 24 what they did, I can't answer that.</p>

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<p>177</p> <p>1 MR. MONTGOMERY: Just a couple more 05:04</p> <p>2 quick ones.</p> <p>3 BY MR. MONTGOMERY:</p> <p>4 Q. You've been the editor in chief of JAMA</p> <p>5 now for seven years; is that right? 05:04</p> <p>6 A. Correct, seven years and eleven days.</p> <p>7 Q. Would you say that experience has left</p> <p>8 you well qualified to opine about what should and</p> <p>9 should not be included in medical journal</p> <p>10 articles? 05:04</p> <p>11 A. Yes.</p> <p>12 Q. And do you believe that that experience</p> <p>13 has left you well qualified to opine about what</p> <p>14 JAMA's readership expects to be included in</p> <p>15 medical journal articles? 05:04</p> <p>16 A. Yes.</p> <p>17 MR. MONTGOMERY: No further questions.</p> <p>18 MR. NELSON: Are you done?</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>179</p> <p>1 IN THE UNITED STATES DISTRICT COURT</p> <p>2 DISTRICT OF NEW JERSEY</p> <p>3</p> <p>4 Alaska Electrical, et al. v. Pharmacia, et al.</p> <p>5 Case No. 03-1519</p> <p>6</p> <p>7 I hereby certify that I have read the</p> <p>8 foregoing transcript of my deposition given on</p> <p>9 January 12, 2007, consisting of Pages 1 - 178</p> <p>10 inclusive, and I do again subscribe and make oath</p> <p>11 that the same is a true, correct, and complete</p> <p>12 transcript of my deposition so given as aforesaid, as</p> <p>13 it now appears.</p> <p>14</p> <p>15 PLEASE CHECK ONE:</p> <p>16 ___ I have no corrections.</p> <p>17 ___ Number of errata sheets enclosed.</p> <p>18</p> <p>19 _____</p> <p>20 CATHERINE DE ANGELIS</p> <p>21 Subscribed and sworn to</p> <p>22 before me this ____ day</p> <p>23 of _____, 2007.</p> <p>24 _____</p>
<p>178</p> <p>1 FURTHER EXAMINATION 05:05</p> <p>2 BY MR. HALPER:</p> <p>3 BY MR. HALPER:</p> <p>4 Q. Do you know the relationship between</p> <p>5 JAMA's readership and the investment community? 05:05</p> <p>6 A. I know the investment community has</p> <p>7 subscriptions. That's all I know.</p> <p>8 Q. Do you know the extent of those</p> <p>9 subscriptions?</p> <p>10 A. No. I don't know numbers. I do know 05:05</p> <p>11 they, the reason I know is because I was astounded</p> <p>12 that they bothered to read it, but they do.</p> <p>13 Q. But you can't opine on how whatever that</p> <p>14 readership is translates into any impact on the</p> <p>15 stock market; correct? 05:05</p> <p>16 A. No, I can't. I don't know.</p> <p>17 MR. HALPER: No further questions.</p> <p>18 MR. MONTGOMERY: All right. We can</p> <p>19 conclude the deposition at this time.</p> <p>20 THE VIDEOGRAPHER: This will conclude 05:05</p> <p>21 Videotape No. 5 and the videotaped deposition at</p> <p>22 this time. The time now is 5:05 p.m.</p> <p>23 (WHEREUPON said deposition was so</p> <p>24 concluded.)</p>	<p>180</p> <p>1 ERRATA SHEET</p> <p>2 DEPOSITION OF: CATHERINE DE ANGELIS</p> <p>3 DATE: January 12, 2007</p> <p>4</p> <p>5 PAGE LINE NUMBER COMMENT</p> <p>6 _____</p> <p>7 _____</p> <p>8 _____</p> <p>9 _____</p> <p>10 _____</p> <p>11 _____</p> <p>12 _____</p> <p>13 _____</p> <p>14 _____</p> <p>15 _____</p> <p>16 _____</p> <p>17 _____</p> <p>18 _____</p> <p>19 _____</p> <p>20 _____</p> <p>21 _____</p> <p>22 _____</p> <p>23</p> <p>24 DATE: _____ SIGNATURE: _____</p>

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<p>181</p> <p>1 STATE OF ILLINOIS ) 2 COUNTY OF C O O K ) 3 4 I, Donna M. Stifter, RPR, CSR No. 5 084-003145, do hereby certify: 6 That the foregoing deposition of CATHERINE DE 7 ANGELIS was taken before me at the time and place 8 therein set forth, at which time the witness was 9 put under oath by me; 10 That the testimony of the witness and all 11 objections made at the time of the examination 12 were recorded stenographically by me, were 13 thereafter transcribed under my direction and 14 supervision and that the foregoing is a true 15 record of same. 16 I further certify that I am neither counsel 17 for nor related to any party to said action, nor 18 in any way interested in the outcome thereof. 19 IN WITNESS WHEREOF, I have subscribed my name 20 this _____ day of January, 2007. 21 _____ 22 23 Donna M. Stifter, RPR, CSR 084-003145 24</p>	<p>183</p> <p>1 DEPOSITION EXHIBITS 2 CATHERINE DE ANGELIS 3 NUMBER DESCRIPTION PAGE 4 5 17 Subpoena 10 6 7 18 Curriculum Vitae 12 8 9 3 9/13/00 article, 10 "Gastrointestinal Toxicity 11 With Celecoxib vs. 12 Nonsteroidal Anti-inflammatory 13 Drugs for Osteoarthritis 14 and Rheumatoid Arthritis. 15 The CLASS Study: A 16 Randomized Controlled 17 Trial 19 18 19 19 11/1/01 letter, White 20 to Charlesworth, 00111092 21 - 00111094 21 22 23 20 photocopy of Drs. Friedman 24 and Verburg cards 28</p>
<p>182</p> <p>1 I N D E X 2 3 Friday, January 12, 2007 4 5 WITNESS EXAMINATION 6 7 CATHERINE DE ANGELIS 8 (By Mr. Montgomery) 5 9 (By Mr. Halper) 116 10 (By Mr. Montgomery) 176 11 (By Mr. Halper) 178 12 13 14 15 16 17 18 19 20 21 22 23 24</p>	<p>184</p> <p>1 DEPOSITION EXHIBITS 2 CATHERINE DE ANGELIS 3 NUMBER DESCRIPTION PAGE 4 5 21 Final Report of the 6 CLASS study, 01220923 - 7 01221137 33 8 9 22 5/22/01 e-mail chain, 10 Wahba to Cristo, 11 00500695 - 00500697 38 12 13 8 8/5/01 Washington Post 14 article, "Missing Data On 15 Celebrex; Full Study 16 Altered Picture Of Drug" 43 17 18 23 8/22 Wall Street Journal 19 article, "Study Hikes 20 Specter of Arthritis 21 Pills' Side Effect," 22 00277868 - 00277872 48 23 24</p>

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# EXHIBIT 10



<p>1 IN THE UNITED STATES DISTRICT COURT</p> <p>2 DISTRICT OF NEW JERSEY</p> <p>3 _____</p> <p>4 ALASKA ELECTRICAL PENSION FUND, )</p> <p>5 et. al., )</p> <p>6 Plaintiffs, )</p> <p>7 vs. ) No. 03-1519</p> <p>8 PHARMACIA CORPORATION, et. al., )</p> <p>9 Defendants. )</p> <p>10 _____)</p> <p>11 Videotaped deposition of DR. DRUMMOND</p> <p>12 RENNIE, called by the Plaintiffs for examination,</p> <p>13 taken pursuant to subpoena, and by the provisions</p> <p>14 of the Rules of Civil Procedure for the United</p> <p>15 States District Courts pertaining to the taking</p> <p>16 of depositions, taken before DEBORAH HABIAN,</p> <p>17 CSR No. 084-002432, a Notary Public within and</p> <p>18 for the County of Cook, State of Illinois, and a</p> <p>19 Certified Shorthand Reporter of said State, at</p> <p>20 the offices of the American Medical Association,</p> <p>21 515 North State Street, 14th Floor, Chicago,</p> <p>22 Illinois, on the 18th day of January, 2007, at</p> <p>23 1:30 p.m.</p> <p>24</p>	<p>1 APPEARANCES: (Cnt'd)</p> <p>2</p> <p>3 AMERICAN MEDICAL ASSOCIATION</p> <p>4 BY: LEONARD A. NELSON, ESQ.</p> <p>5 515 North State Street</p> <p>6 Chicago, Illinois 60610</p> <p>7 (312) 464-5532</p> <p>8 on behalf of deponent.</p> <p>9</p> <p>10 ALSO PRESENT:</p> <p>11 EASTWOOD-STEIN DEPOSITION MANAGEMENT</p> <p>12 BY: DAVID GILLERAN, VIDEOGRAPHER</p> <p>13 11 South LaSalle Street, Suite 900,</p> <p>14 Chicago, Illinois 60603</p> <p>15 (800) 343-0733</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
<p>1 APPEARANCES:</p> <p>2</p> <p>3 LERACH COUGHLIN STOIA GELLER</p> <p>4 RUDMAN &amp; ROBBINS, LLP</p> <p>5 BY: MATTHEW MONTGOMERY, ESQ.</p> <p>6 655 West Broadway, Suite 1900</p> <p>7 San Diego, California 92101-3301</p> <p>8 (619) 231-1058</p> <p>9 on behalf of the Plaintiffs;</p> <p>10</p> <p>11 CADWALADER WICKERSHAM &amp; TAFT, LLP</p> <p>12 BY: JASON M. HALPER, ESQ.</p> <p>13 KATHERINE A. RITCHIE, ESQ.</p> <p>14 One World Financial Center</p> <p>15 New York, New York 10281</p> <p>16 (212) 504-6605</p> <p>17 on behalf of the Defendants</p> <p>18 Pharmacia Corporation;</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 I N D E X</p> <p>2 WITNESS: DX CX RDX RCX</p> <p>3 DR. DRUMMOND RENNIE</p> <p>4 BY: MR. MATTHEW MONTGOMERY 08 190</p> <p>5 BY: MR. JASON M. HALPER 122 ---</p> <p>6</p> <p>7</p> <p>8 PLAINTIFFS EXHIBITS PAGE</p> <p>9 No. 3 ..... 23</p> <p>No. 4 ..... 62</p> <p>10 No. 21 ..... 107</p> <p>No. 22 ..... 52</p> <p>11 No. 24 ..... 89</p> <p>No. 27 ..... 93</p> <p>12 No. 28 ..... 58</p> <p>No. 31 ..... 82</p> <p>13 No. 32 ..... 115</p> <p>No. 36 ..... 68</p> <p>14 No. 37 ..... 100</p> <p>No. 38 ..... 102</p> <p>15 No. 39 ..... 91</p> <p>No. 40 ..... 118</p> <p>16 No. 42 ..... 29</p> <p>No. 43 ..... 11</p> <p>17 No. 44 ..... 14</p> <p>No. 45 ..... 36</p> <p>18 No. 46 ..... 47</p> <p>No. 47 ..... 65</p> <p>19 No. 48 ..... 72</p> <p>No. 49 ..... 77</p> <p>20 No. 50 ..... 79</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

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<p>5</p> <p>1 THE VIDEOGRAPHER: For the record my name</p> <p>2 is David Gilleran. I'm working in conjunction</p> <p>3 with Eastwood-Stein Deposition Management, 11</p> <p>4 South LaSalle Street, Suite 900, Chicago,</p> <p>5 Illinois.</p> <p>6 This deposition is being videorecorded</p> <p>7 pursuant to Federal Rule 30(b) and all other</p> <p>8 applicable state and local rules.</p> <p>9 We are at 515 North State Street,</p> <p>10 Chicago, Illinois to take the videotaped</p> <p>11 deposition of Dr. Drummond Rennie in the matter</p> <p>12 of Alaska Electrical Pension Fund Et. Al. vs.</p> <p>13 Pharmacia Corporation, Et. Al,</p> <p>14 Court No. 03-1519 in the U.S. District Court,</p> <p>15 District of New Jersey.</p> <p>16 Today's date is January 18, 2007, the</p> <p>17 time is 1:33 p.m. This is taking place on behalf</p> <p>18 of Plaintiff; is that correct?</p> <p>19 MR. MONTGOMERY: That's correct.</p> <p>20 THE VIDEOGRAPHER: This deposition is being</p> <p>21 videotaped on the behalf of the Plaintiff, it is</p> <p>22 being taken at the instance of the Plaintiff.</p> <p>23 And if the court reporter could swear in the</p> <p>24 witness and if the parties would like to identify</p>	<p>7</p> <p>1 And the reason they brought this suit is that</p> <p>2 they contend that the Defendants, which are</p> <p>3 Pharmacia Corporation, Pfizer and some of the</p> <p>4 employees of those companies, made</p> <p>5 misrepresentations about the drug Celebrex during</p> <p>6 that time period, and their contention is that,</p> <p>7 by misrepresenting the side effects of the drug,</p> <p>8 they inflated the price of Pharmacia stock so</p> <p>9 that my clients paid too much money for the</p> <p>10 stock, and when the truth about Celebrex came</p> <p>11 out, the price of the stock dropped and my</p> <p>12 clients lost a lot of money.</p> <p>13 Now, Defendants in this case dispute</p> <p>14 all of those allegations, but that's what we're</p> <p>15 here today about.</p> <p>16 First of all, I'd like to thank you</p> <p>17 for being here and let you know I'm going to try</p> <p>18 and get the information that I need and get you</p> <p>19 out of here as soon as possible.</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
<p>6</p> <p>1 themselves for the record?</p> <p>2 THE REPORTER: Raise your right hand,</p> <p>3 Doctor.</p> <p>4 (Witness sworn.)</p> <p>5 THE REPORTER: Thank you.</p> <p>6 MR. MONTGOMERY: Matthew Montgomery from</p> <p>7 Lerach, Coughlin representing the Plaintiffs.</p> <p>8 MR. HALPER: Jason Halper, Cadawalder, for</p> <p>9 the Defendants. And just to clarify, we cross</p> <p>10 noticed the deposition.</p> <p>11 MS. RITCHIE: Katherine Ritchie of</p> <p>12 Cadwalader for the Defendants.</p> <p>13 MR. NELSON: My name is Leonard Nelson. I'm</p> <p>14 an employee of the American Medical Association.</p> <p>15 I represent the deponent.</p> <p>16 MR. MONTGOMERY: Good morning, Dr. Rennie.</p> <p>17 Afternoon. Could you state your name for the</p> <p>18 record, please?</p> <p>19 THE WITNESS: Drummond Rennie.</p> <p>20 MR. MONTGOMERY: All right, just to clarify</p> <p>21 or so you understand what we're doing here, I</p> <p>22 represent the Plaintiffs in this case, and there</p> <p>23 are a number of pension funds that bought stock</p> <p>24 in Pharmacia Corporation between 2000 and 2002.</p>	<p>8</p> <p>1 DR. DRUMMOND RENNIE,</p> <p>2 called as a witness herein by the Plaintiffs,</p> <p>3 having been first duly sworn, was examined and</p> <p>4 testified as follows:</p> <p>5 DIRECT EXAMINATION</p> <p>6 BY MR. MONTGOMERY:</p> <p>7 Q Have you ever been deposed before?</p> <p>8 A Yes.</p> <p>9 Q How many times?</p> <p>10 A Six times, say, seven, eight.</p> <p>11 Q Okay, so have you ever been deposed in</p> <p>12 a securities fraud action before?</p> <p>13 A No.</p> <p>14 Q All right, you have done this before,</p> <p>15 so I'll make this very brief. Do you understand</p> <p>16 that the oath that you just took has the same</p> <p>17 force and effect here as it would in a court of</p> <p>18 law?</p> <p>19 A Yes.</p> <p>20 Q All right, you can see the court</p> <p>21 reporter is going to be typing my questions, any</p> <p>22 objections and your answers. So it's important</p> <p>23 that you let me finish my questions and any</p> <p>24 objections that one of the other attorneys might</p>

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<p>9</p> <p>1 want to put on the record before you answer it.</p> <p>2 Do you understand?</p> <p>3 A Yes.</p> <p>4 Q Okay. Now, I'd like to define a few</p> <p>5 terms so it will be easier for us as we go along.</p> <p>6 Are you familiar with the drug commercially known</p> <p>7 as Celebrex?</p> <p>8 A Yes.</p> <p>9 Q And are you aware that its chemical</p> <p>10 name, if that's the right term, is celecoxib?</p> <p>11 A Yes.</p> <p>12 Q Okay, so I'm going to use those terms</p> <p>13 interchangeably if that's okay with you?</p> <p>14 A Yes.</p> <p>15 Q Are you familiar with the celecoxib</p> <p>16 Long-Term Arthritis Safety Study?</p> <p>17 A Yes.</p> <p>18 Q And I'm going to refer to that also as</p> <p>19 the class study during your deposition, if that's</p> <p>20 okay?</p> <p>21 A Yes.</p> <p>22 Q I'm also going to be referring to the</p> <p>23 Journal of the American Medical Association as</p> <p>24 JAMA, if that's all right with you?</p>	<p>11</p> <p>1 establish what we're going to call it. Can you</p> <p>2 put on the -- is that all right with you that you</p> <p>3 understand that?</p> <p>4 A Oh, yes, of course.</p> <p>5 MR. MONTGOMERY: Okay. All right, at this</p> <p>6 point, I would like to ask the court reporter to</p> <p>7 mark what would be Exhibit 43.</p> <p>8 THE WITNESS: Thank you.</p> <p>9 MR. MONTGOMERY: For the record, Exhibit 43</p> <p>10 is the subpoena pursuant to which Dr. Rennie is</p> <p>11 appearing today.</p> <p>12 (Deposition Exhibit No. 43</p> <p>13 was marked for ID)</p> <p>14 MR. NELSON: Mr. Montgomery, would it be</p> <p>15 better if the court reporter were just to keep</p> <p>16 the originals and I were to give the copies to</p> <p>17 the witness?</p> <p>18 MR. MONTGOMERY: I'd rather have him look at</p> <p>19 the actual --</p> <p>20 MR. NELSON: Okay.</p> <p>21 MR. MONTGOMERY: (Continuing) -- exhibits</p> <p>22 that are attached --</p> <p>23 MR. NELSON: Okay.</p> <p>24 MR. MONTGOMERY: (Continuing) -- just in</p>
<p>10</p> <p>1 A Yes.</p> <p>2 Q And as I explained before, the</p> <p>3 Defendants in this case are Pfizer, Pharmacia and</p> <p>4 certain of their employees. So if I refer to</p> <p>5 Defendants, do you understand that that's who I'm</p> <p>6 referring to?</p> <p>7 A Yes.</p> <p>8 Q Okay, to the extent that any of those</p> <p>9 things might be confusing or might not be</p> <p>10 applicable in your opinion later on, just let me</p> <p>11 know, and I can be more specific if something</p> <p>12 comes up.</p> <p>13 A Are we going to get into a discussion</p> <p>14 of what you mean by familial?</p> <p>15 Q Not unless you are confused by the</p> <p>16 term. And do you have a general understanding of</p> <p>17 that term?</p> <p>18 A Well, familiarity with a class study</p> <p>19 could be quite a lot of things, couldn't it?</p> <p>20 Q Sure. For these -- for the purposes</p> <p>21 of the question that I was just asking, I suppose</p> <p>22 just being aware of the study.</p> <p>23 A I'm aware of the study.</p> <p>24 Q Okay, because I was just trying to</p>	<p>12</p> <p>1 case there's a missing page, accident, anything.</p> <p>2 MR. NELSON: Fine.</p> <p>3 BY MR. MONTGOMERY:</p> <p>4 Q Dr. Rennie, have you seen this</p> <p>5 document before?</p> <p>6 A Yes.</p> <p>7 Q Would you turn to the last page of</p> <p>8 Exhibit 43, please?</p> <p>9 A (Witness so doing).</p> <p>10 Q Do you see under "Document</p> <p>11 Requested" -- "Documents Requested" on that page</p> <p>12 there's a Request No. 2?</p> <p>13 A Yes.</p> <p>14 Q Okay, and that reads, "All documents</p> <p>15 concerning the class study"?</p> <p>16 A Yes.</p> <p>17 Q Did you personally do anything to look</p> <p>18 for documents --</p> <p>19 A Yes.</p> <p>20 Q Let me -- you got to let me finish my</p> <p>21 question first. Did you personally do anything</p> <p>22 to look for documents responsive to this request?</p> <p>23 Now you can answer.</p> <p>24 A Yes.</p>

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<p>13</p> <p>1 Q And what did you do?</p> <p>2 A I looked for documents concerning the</p> <p>3 class study.</p> <p>4 Q And where did you look for those</p> <p>5 documents?</p> <p>6 A I looked for them in my files, my</p> <p>7 computer files.</p> <p>8 Q Did you find any?</p> <p>9 A I found -- yes.</p> <p>10 Q And what did you find?</p> <p>11 A I found slides.</p> <p>12 Q How many approximately?</p> <p>13 A Three.</p> <p>14 Q Did you find anything else?</p> <p>15 A No.</p> <p>16 MR. MONTGOMERY: All right, I would now like</p> <p>17 to ask the court reporter to mark what will be</p> <p>18 Exhibit 44.</p> <p>19 THE WITNESS: Am I allowed to talk to my</p> <p>20 attorney?</p> <p>21 MR. MONTGOMERY: We can take a break at</p> <p>22 certain points. You really can't confer during</p> <p>23 the deposition unless it's a question of whether</p> <p>24 something's --</p>	<p>15</p> <p>1 like what happened before, feel free to let me</p> <p>2 know, and I'll clarify or --</p> <p>3 A Yeah.</p> <p>4 Q -- rephrase the question. Also if you</p> <p>5 need to take a break at any time, that's fine. I</p> <p>6 would like -- if we're in the middle of a series</p> <p>7 of questions, I would like to finish those up,</p> <p>8 but then we can take any breaks that are</p> <p>9 necessary.</p> <p>10 All right, now, turning to Exhibit 44</p> <p>11 in front of you, does this appear to be a copy of</p> <p>12 your curriculum vitae?</p> <p>13 A Yes, but the bottom's legally --</p> <p>14 Q Yes.</p> <p>15 A -- struck out.</p> <p>16 Q Yeah, it's a little cut off, right?</p> <p>17 A It's because of legal pages being</p> <p>18 longer than --</p> <p>19 Q I see.</p> <p>20 A -- normal pages.</p> <p>21 Q Other than that, as far as you know,</p> <p>22 does it --</p> <p>23 A Yeah.</p> <p>24 Q -- appear to be up-to-date?</p>
<p>14</p> <p>1 MR. NELSON: Well, do you want --</p> <p>2 MR. MONTGOMERY: Sure.</p> <p>3 MR. NELSON: This is not critical. We're</p> <p>4 not interrupting anything.</p> <p>5 MR. MONTGOMERY: Certainly not.</p> <p>6 MR. NELSON: So since the witness has a</p> <p>7 question, let's take a short break, Dr. Rennie,</p> <p>8 and I'll step outside with you because if there's</p> <p>9 a matter of a concern, let's talk about it.</p> <p>10 MR. MONTGOMERY: Yeah, let's go off the</p> <p>11 record, please.</p> <p>12 (Recess taken off the record.)</p> <p>13 (Deposition Exhibit No. 44</p> <p>14 was marked for ID)</p> <p>15 MR. MONTGOMERY: All right, back on the</p> <p>16 record, please.</p> <p>17 THE VIDEOGRAPHER: Recording.</p> <p>18 BY MR. MONTGOMERY:</p> <p>19 Q All right, Dr. Rennie, do you</p> <p>20 understand you're still under oath?</p> <p>21 A I do.</p> <p>22 Q Okay. Now, if at any point I ask any</p> <p>23 question that you're not comfortable with, maybe</p> <p>24 you don't understand one of the terms I'm using</p>	<p>16</p> <p>1 A I believe it to be up-to-date. It --</p> <p>2 it's the latest version I have.</p> <p>3 Q All right, on the bottom of the first</p> <p>4 page of Exhibit 44, there's a section for</p> <p>5 "Present Positions Held". Do you see that?</p> <p>6 A Yes.</p> <p>7 Q And as you noted, some parts of that</p> <p>8 have been cut off. Is one of the positions that</p> <p>9 would be listed there if it were complete the --</p> <p>10 a position at JAMA?</p> <p>11 A Yes.</p> <p>12 Q And what is that position?</p> <p>13 A Deputy Editor.</p> <p>14 Q And do you currently hold that</p> <p>15 position?</p> <p>16 A Yes.</p> <p>17 Q How long have you had it?</p> <p>18 A I've had the same job since 1988 or</p> <p>19 since 1983. It's a matter of what it was called.</p> <p>20 Q What was it called in 1983?</p> <p>21 A Associate Editor.</p> <p>22 Q And have your responsibilities changed</p> <p>23 appreciably from 1983 to the present?</p> <p>24 A In no way.</p>

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<p>17</p> <p>1 Q And what are your specific</p> <p>2 responsibilities at JAMA?</p> <p>3 A I -- my first task is to read the</p> <p>4 manuscripts that are sent in to assess their</p> <p>5 scientific validity and importance, to have them</p> <p>6 reviewed or not by experts that I know to assess</p> <p>7 those and to improve the very few we accept and</p> <p>8 to, well, select them and to improve them, and</p> <p>9 then to do a whole slew of other things which</p> <p>10 have to do with editorial matters, but not</p> <p>11 administrative ones because I'm at the University</p> <p>12 of California in San Francisco, and that was the</p> <p>13 deal.</p> <p>14 Q Do you review manuscripts about a</p> <p>15 particular medical area?</p> <p>16 A They tend -- the answer's yes, sort</p> <p>17 of. I tend to be sent manuscripts that are</p> <p>18 within my specialty, which is of renal disease</p> <p>19 and things that interest me, for example,</p> <p>20 statistical and epidemiologic problems that we</p> <p>21 aren't supposed to have in general and of</p> <p>22 certainly areas like that, areas of particular</p> <p>23 interest to me.</p> <p>24 Q Who chooses the articles that are sent</p>	<p>19</p> <p>1 understanding of what information should and</p> <p>2 maybe should not be included in medical journal</p> <p>3 articles?</p> <p>4 MR. HALPER: Objection to form.</p> <p>5 THE WITNESS: That's a very full question,</p> <p>6 and I can expand on that, if you wish.</p> <p>7 BY MR. MONTGOMERY:</p> <p>8 Q Please.</p> <p>9 A If I'm being sent an editorial, then I</p> <p>10 know that's an opinion. If I'm sent a</p> <p>11 commentary, that's an opinion, and I'll allow a</p> <p>12 lot -- my opinion will be to allow a great deal</p> <p>13 more laxity.</p> <p>14 If I'm being sent a paper that</p> <p>15 examines, say, the health effects of</p> <p>16 post-menopausal hormones on thousands of women,</p> <p>17 I'll demand much higher, rigorous standards. If</p> <p>18 I'm sent one on a randomized trial where</p> <p>19 everything can be very well defined beforehand,</p> <p>20 not only can, but must be, I'll demand a higher</p> <p>21 standard still.</p> <p>22 Q Let me be more specific then. Do you</p> <p>23 believe, based on your experience, that you have</p> <p>24 an understanding of what sort of data from</p>
<p>18</p> <p>1 to you to review?</p> <p>2 A One of the editors in situ here, which</p> <p>3 I believe is either Dr. Phil Fontanarosa or</p> <p>4 Dr. Richard Glass. But I never know in any one</p> <p>5 week who that is, ever, and for all I know, it</p> <p>6 may be others.</p> <p>7 Q I believe that you said one of your</p> <p>8 areas of interest is statistical analyses; is</p> <p>9 that correct?</p> <p>10 A The more general way of putting it is</p> <p>11 that I started an initiative which has to do with</p> <p>12 the -- examining the quality of articles that</p> <p>13 come into journals in general and the way these</p> <p>14 are handled by journals and the quality of</p> <p>15 journals, and I started that in 1986.</p> <p>16 And that's become a large deal. And</p> <p>17 because of this known enthusiasm, I tend to get</p> <p>18 sent through JAMA papers, for example, pointing</p> <p>19 out issues that randomized clinical trials might</p> <p>20 have or what are called observational studies</p> <p>21 might have. They tend to get routed in my</p> <p>22 direction.</p> <p>23 Q Based upon your experience at JAMA and</p> <p>24 in academia, do you believe that you have an</p>	<p>20</p> <p>1 randomized trials should be included in journal</p> <p>2 articles?</p> <p>3 MR. HALPER: Objection to form.</p> <p>4 THE WITNESS: Yes.</p> <p>5 BY MR. MONTGOMERY:</p> <p>6 Q Based on your experience, do you</p> <p>7 believe you have an understanding of what sorts</p> <p>8 of data the readers of JAMA expect to be included</p> <p>9 in articles that are published in the journal?</p> <p>10 MR. HALPER: Objection to form.</p> <p>11 THE WITNESS: It depends which readers</p> <p>12 you're talking about. The answer is yes, and I'd</p> <p>13 like to think all. The answer also is it depends</p> <p>14 on the reader.</p> <p>15 BY MR. MONTGOMERY:</p> <p>16 Q What sorts of readers do you believe</p> <p>17 you have an understanding of their expectations?</p> <p>18 A Perhaps, I should give an illustration</p> <p>19 here.</p> <p>20 MR. NELSON: Well, let him ask for the</p> <p>21 illustration. I think you should really say if</p> <p>22 you can answer the question -- I mean it -- just,</p> <p>23 you know, it was an obviously difficult question</p> <p>24 to answer.</p>

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<p>21</p> <p>1 THE WITNESS: Yeah.</p> <p>2 MR. NELSON: And if you said, I don't</p> <p>3 understand it, I can't formulate an answer the</p> <p>4 way it's phrased, then it will be Counsel's, you</p> <p>5 know, burden to rephrase it.</p> <p>6 THE WITNESS: Perhaps -- Mr. Montgomery,</p> <p>7 perhaps you'd --</p> <p>8 MR. MONTGOMERY: Sure.</p> <p>9 THE WITNESS: (Continuing) say it again</p> <p>10 or --</p> <p>11 BY MR. MONTGOMERY:</p> <p>12 Q Maybe it would be easier to approach</p> <p>13 it from are there specific types of readers of</p> <p>14 JAMA whose expectations you think you might be</p> <p>15 unfamiliar with?</p> <p>16 MR. HALPER: Objection to form.</p> <p>17 THE WITNESS: That, I -- I don't know. I</p> <p>18 don't know, but I would have thought, and this is</p> <p>19 pure speculation, that if you're a patient, you'd</p> <p>20 have a lot of difficulty reading a trial or</p> <p>21 critiquing it, which is another issue.</p> <p>22 BY MR. MONTGOMERY:</p> <p>23 Q All right, over the years, have you</p> <p>24 had regular communications with clinicians that</p>	<p>23</p> <p>1 to be included in JAMA articles?</p> <p>2 A Yes.</p> <p>3 MR. HALPER: Object to the form.</p> <p>4 BY MR. MONTGOMERY:</p> <p>5 Q I'd like to show the witness what's</p> <p>6 previously been marked as Exhibit 3.</p> <p>7 A Thank you.</p> <p>8 Q Before we turn to Exhibit 3, I'd like</p> <p>9 to ask one more question along the lines that we</p> <p>10 were talking about before.</p> <p>11 You stated that, is it correct, that</p> <p>12 in your experience clinicians reading JAMA expect</p> <p>13 all relevant data to be included from clinical</p> <p>14 trials and articles? Is that correct?</p> <p>15 MR. HALPER: Objection to form.</p> <p>16 THE WITNESS: Yeah.</p> <p>17 BY MR. MONTGOMERY:</p> <p>18 Q Do you believe that you're qualified</p> <p>19 to assess what data in a particular study is</p> <p>20 relevant and should be included in JAMA articles?</p> <p>21 A Yes.</p> <p>22 MR. HALPER: Objection to form.</p> <p>23 BY MR. MONTGOMERY:</p> <p>24 Q Okay, turning to Exhibit 3, have you</p>
<p>22</p> <p>1 read JAMA for their own medical practices?</p> <p>2 A Yes.</p> <p>3 Q And based upon those conversations, do</p> <p>4 you feel that you have an understanding of what</p> <p>5 sorts of data those clinicians expect to be</p> <p>6 included in JAMA articles about randomized</p> <p>7 trials?</p> <p>8 A No.</p> <p>9 Q So do you have any idea what sorts of</p> <p>10 data they expect --</p> <p>11 A Yes.</p> <p>12 Q -- to be included?</p> <p>13 A Yes. In a nutshell, the complaint is</p> <p>14 that medicine is too complicated and getting more</p> <p>15 so, and they'd like it less so.</p> <p>16 Q My question was less about what their</p> <p>17 preferences would be and more about what their</p> <p>18 expectations about what is and is not included.</p> <p>19 A The two tend to be muddled, don't</p> <p>20 they? And their expectation is, of course, that</p> <p>21 they get absolutely everything, but that's also</p> <p>22 their complaint.</p> <p>23 Q So in your experience, the clinicians</p> <p>24 that read JAMA expect all relevant clinical data</p>	<p>24</p> <p>1 seen this before?</p> <p>2 A Yes.</p> <p>3 Q Is it a copy of an article from JAMA</p> <p>4 concerning the class study?</p> <p>5 A Yes.</p> <p>6 Q And for the purposes of our</p> <p>7 deposition, I'm just going to call this the JAMA</p> <p>8 article, if that's okay with you?</p> <p>9 A Yes.</p> <p>10 Q If that gets confusing, if there are</p> <p>11 other articles, let me know and we'll try to</p> <p>12 straighten it out as we go along.</p> <p>13 Do you recall the first time that you</p> <p>14 heard about the class study?</p> <p>15 A Yes.</p> <p>16 Q When was that?</p> <p>17 A When I read my journal.</p> <p>18 Q So the first time you read Exhibit 3</p> <p>19 was the first time you heard about the class</p> <p>20 study; is that correct?</p> <p>21 A Yes.</p> <p>22 Q So I take it then that you did not</p> <p>23 participate in any of the editorial process</p> <p>24 regarding Exhibit 3 before it was published in</p>

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<p>25</p> <p>1 JAMA?</p> <p>2 A No, I did not.</p> <p>3 Q After the publication of Exhibit 3,</p> <p>4 did you have occasion to speak for JAMA</p> <p>5 concerning this article in any forum?</p> <p>6 A No, and -- yes, I spoke. I did not</p> <p>7 speak for JAMA. I think in every case, I make</p> <p>8 that very clear.</p> <p>9 Q Did you take any steps at the</p> <p>10 direction of JAMA concerning the JAMA article?</p> <p>11 A I don't understand the question.</p> <p>12 Q Did anyone at JAMA ask you to do</p> <p>13 anything having to do with this article,</p> <p>14 Exhibit 3?</p> <p>15 A No.</p> <p>16 Q After Exhibit 3 was published, did you</p> <p>17 have occasion to look into the context in which</p> <p>18 it was published or the -- let me -- let me</p> <p>19 rephrase. Strike that question.</p> <p>20 After the publication of Exhibit 3,</p> <p>21 did you have occasion to look into the details of</p> <p>22 the class study?</p> <p>23 A Yes.</p> <p>24 Q And what prompted that?</p>	<p>27</p> <p>1 about the class study.</p> <p>2 And I was upset -- no, I was -- well,</p> <p>3 the technical term was I was pissed off that</p> <p>4 there seemed to be a discrepancy. But, again, I</p> <p>5 had nothing to do with it, and I was aware that</p> <p>6 my colleagues were worrying about this, and they</p> <p>7 were the ones who could do something about it. I</p> <p>8 didn't draw this to their attention.</p> <p>9 Q What did you do that led you to the</p> <p>10 conclusion that there was some sort of</p> <p>11 discrepancy?</p> <p>12 A This must be, my guess would be, the</p> <p>13 beginning of 2001 that for one reason or another,</p> <p>14 and I'm hazarding a guess here, I had the</p> <p>15 feeling -- I sort of vaguely remember a lawsuit</p> <p>16 or a -- or perhaps it was just a Freedom of</p> <p>17 Information Request to the FDA filed by something</p> <p>18 like Public Citizen or whatever which caused the</p> <p>19 full details of what was not just one, but two</p> <p>20 trials of differing lengths and much longer than</p> <p>21 this to be put in the public domain. And then it</p> <p>22 is no surprise at all to find that those who read</p> <p>23 that blame the editors for not knowing this.</p> <p>24 Q When you say --</p>
<p>26</p> <p>1 A I got -- now, I'm remembering</p> <p>2 something I have not looked up. Indeed, I</p> <p>3 haven't looked this up (indicating).</p> <p>4 I got an e-mail from somebody in</p> <p>5 British Columbia called Wright, with a W, who was</p> <p>6 a member of the Cochrane Collaboration, which is</p> <p>7 a very large organization from -- in which I take</p> <p>8 a prominent role. And on that basis, he -- he</p> <p>9 claimed there was something wrong with this</p> <p>10 study, and he demanded because he knew me that</p> <p>11 something be put right. I'm trying to remember.</p> <p>12 And I told him, You're up -- I'm the</p> <p>13 wrong person, you write a letter to the editor,</p> <p>14 that's what people do. And most people who write</p> <p>15 to editors are very angry, and I expect I asked</p> <p>16 him what part of write a letter to the editor he</p> <p>17 didn't understand, and that was that.</p> <p>18 Q Subsequent to that conversation, did</p> <p>19 you have occasion to look into the details of the</p> <p>20 class study?</p> <p>21 A Yes. That conversa -- that</p> <p>22 interchange, I believe it was him, but I can't</p> <p>23 remember, got me or somebody working beside me to</p> <p>24 look into the FDA -- what the FDA had to say</p>	<p>28</p> <p>1 A I seem to remember that, and so I can</p> <p>2 only suppose, but this is a guess. I'm guessing</p> <p>3 how I got there.</p> <p>4 Q When you say -- when said "longer than</p> <p>5 that" in your response, did you mean Exhibit 3,</p> <p>6 the JAMA article?</p> <p>7 A Yeah. And I'm not guessing about some</p> <p>8 things because I made a slide around about then,</p> <p>9 and I'm sure -- it's unlikely, knowing me, I</p> <p>10 believe, that my slide didn't have some backing</p> <p>11 to -- to that. In other words, the FDA disagreed</p> <p>12 with it.</p> <p>13 Q Did you personally look on the FDA's</p> <p>14 website at any data?</p> <p>15 A I'd say I believe so, but I do not</p> <p>16 know. The answer is I don't know.</p> <p>17 Q Based on that, I assume you don't</p> <p>18 recall what specific data you might have looked</p> <p>19 at on the FDA website?</p> <p>20 A Well, no.</p> <p>21 MR. MONTGOMERY: All right, I'd like to ask</p> <p>22 the court reporter to mark what will be</p> <p>23 Exhibit 45.</p> <p>24 THE WITNESS: Thank you.</p>

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<p style="text-align: right;">29</p> <p>1 MR. MONTGOMERY: I'm sorry, this has</p> <p>2 previously been marked as Exhibit 42.</p> <p>3 THE REPORTER: Want to take it back?</p> <p>4 MR. MONTGOMERY: Yes. If you could hand</p> <p>5 that back to the court reporter, she'll fix it.</p> <p>6 THE WITNESS: (Tendering document)</p> <p>7 BY MR. MONTGOMERY:</p> <p>8 Q Let's see, Exhibit 42 is a reflection</p> <p>9 of the slides that you were referring to that you</p> <p>10 created?</p> <p>11 A Right.</p> <p>12 Q And why did you recreate these slides?</p> <p>13 A I'm interested in authorship, which as</p> <p>14 far as academics is where the rubber hits the</p> <p>15 road, and I'm interested in an authorship, and</p> <p>16 I've got many publications on this and I've</p> <p>17 changed things a lot.</p> <p>18 Authorship gets one credit.</p> <p>19 Authorship also means responsibility, without</p> <p>20 being too pompous about it. And here, it seemed</p> <p>21 to me, that the authors had shed their</p> <p>22 responsibility.</p> <p>23 Q And why do you believe that?</p> <p>24 A I believe they did it for commercial</p>	<p style="text-align: right;">31</p> <p>1 MR. MONTGOMERY: Yes.</p> <p>2 THE REPORTER: Okay.</p> <p>3 (Record read.)</p> <p>4 BY MR. MONTGOMERY:</p> <p>5 Q All right, when you said "this was not</p> <p>6 a true representation" --</p> <p>7 A (Indicating document).</p> <p>8 Q -- did you mean Exhibit 3, the JAMA</p> <p>9 article?</p> <p>10 A The JAMA article.</p> <p>11 Q Okay, so going back to Exhibit 42 for</p> <p>12 a second, did you create these slides for any</p> <p>13 particular presentation?</p> <p>14 A Yes.</p> <p>15 Q And do you recall what it was?</p> <p>16 A Well, I'm -- may I just -- I said yes</p> <p>17 too quickly. I created this slide for -- I</p> <p>18 believe, for a -- I got a prize in Washington.</p> <p>19 Q Again, it might be on your CV, if you</p> <p>20 want to refresh your recollection.</p> <p>21 A And they -- the Association of</p> <p>22 American Medical Colleges and so on wanted -- I</p> <p>23 went up to Washington to get this damn thing, and</p> <p>24 I -- they wanted me to give a lecture on this, on</p>
<p style="text-align: right;">30</p> <p>1 reasons, and that was my guess.</p> <p>2 Q I'm sorry, what I meant when I asked</p> <p>3 you why, I meant what basis do you have for</p> <p>4 believing that they didn't live up to their</p> <p>5 responsibilities?</p> <p>6 A At this time, and that's why I'm</p> <p>7 having difficulty remembering exactly what I saw</p> <p>8 on the FDA website, which I visited for all sorts</p> <p>9 of reasons at various times, I can't remember --</p> <p>10 but there was a great deal of publicity about</p> <p>11 this (indicating), and the central point about</p> <p>12 all that was that this (indicating) was not a</p> <p>13 true representation of what had actually</p> <p>14 happened.</p> <p>15 Q By "this", do you mean Exhibit 3, the</p> <p>16 JAMA article?</p> <p>17 A In other words, that my journal had</p> <p>18 not been provided with a face -- a faithful</p> <p>19 representation of what happened, and that, seen</p> <p>20 from the point of view of an editor, is</p> <p>21 upsetting.</p> <p>22 MR. MONTGOMERY: Could you read back his</p> <p>23 previous response?</p> <p>24 THE REPORTER: This one (indicating screen)?</p>	<p style="text-align: right;">32</p> <p>1 this -- on authorship, the responsibilities of</p> <p>2 authorship and so on, and I suspect that this was</p> <p>3 part of that lecture.</p> <p>4 And when I say "suspect", I have it, I</p> <p>5 have these slides, not because I had that</p> <p>6 lecture, but because I've used it since because</p> <p>7 this is by no means isolated. This set of</p> <p>8 occurrences is -- every one is unique, but the</p> <p>9 general point is I've seen it before. We have</p> <p>10 seen it before. Editors see it.</p> <p>11 Q And what is the central point, as you</p> <p>12 understand it?</p> <p>13 A The central point is telling -- giving</p> <p>14 a faithful representation of what the researchers</p> <p>15 believe to be the truth to -- the editors were</p> <p>16 the surrogates for the readers, and therefore, to</p> <p>17 the readers.</p> <p>18 Q And you believe that the JAMA article</p> <p>19 did not represent a faithful presentation of</p> <p>20 information?</p> <p>21 A Yes, on the basis of what my</p> <p>22 colleagues told me, my colleagues in this</p> <p>23 building and what I then read.</p> <p>24 Q And what specifically was that?</p>



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<p>33</p> <p>1 A Well, there were a number of problems</p> <p>2 with this, which I seem -- which I think I listed</p> <p>3 on the slide. The -- I think the FDA made it</p> <p>4 rather more clear than I did, and that's why, as</p> <p>5 I recollect, I either copied or used or made some</p> <p>6 sort of amalgamation of what I thought and what</p> <p>7 the FDA thought. I've not looked this up again.</p> <p>8 Q Okay, well, let's look at the second</p> <p>9 page of Exhibit 42, please.</p> <p>10 A (Witness so doing).</p> <p>11 Q And is that a slide that you</p> <p>12 personally created?</p> <p>13 A Yes.</p> <p>14 Q All right, at the bottom, the very</p> <p>15 last entry, it says, "Sponsors". Do you see</p> <p>16 that?</p> <p>17 A Yes.</p> <p>18 Q And who are you referring to there?</p> <p>19 A I think it was Pharmacia. I can</p> <p>20 check. (Reviewing document). Yes.</p> <p>21 Q All right, after that, you say,</p> <p>22 "laughing to bank"?</p> <p>23 A Yes.</p> <p>24 Q And what did you mean by that?</p>	<p>35</p> <p>1 A -- that's very painful, indeed, to an</p> <p>2 editor to think it once published something that</p> <p>3 doesn't hold up. Not hold up for scientific</p> <p>4 reason, but hold up for unscientific reasons.</p> <p>5 Q On your slide here -- well, before we</p> <p>6 move on, following up to your last response, when</p> <p>7 you said there were tremendous sales, did you</p> <p>8 mean sales of Celebrex?</p> <p>9 A There was a tune, yes.</p> <p>10 Q All right, going back to your slide,</p> <p>11 the second page of Exhibit 42, there's a line</p> <p>12 item toward the bottom of that page, the second</p> <p>13 page that says "Editors"?</p> <p>14 A Yes.</p> <p>15 Q And were you referring to the editors</p> <p>16 of JAMA?</p> <p>17 A Yes.</p> <p>18 Q And after that, it says, "exasperated,</p> <p>19 furious"?</p> <p>20 A Yes.</p> <p>21 Q Was that characterizing the response</p> <p>22 of the JAMA editors?</p> <p>23 A Well, certainly one of them. Two of</p> <p>24 them, actually.</p>
<p>34</p> <p>1 A The total of what I meant is this: It</p> <p>2 took a long time between the publication in JAMA,</p> <p>3 which is a very difficult thing to get, and the</p> <p>4 revelation in our Letters to the Editor that</p> <p>5 something had gone wrong and also the FDA</p> <p>6 website.</p> <p>7 And during that time, which may have</p> <p>8 been six months, nine months, as I remember,</p> <p>9 there was a very considerable advertising going</p> <p>10 on, which was relevant to me because I'm a</p> <p>11 third-rate climber, but I've been on a very large</p> <p>12 number of big expeditions all over the world,</p> <p>13 third-rate because I don't climb enough, and I</p> <p>14 need something for all the things I've damaged.</p> <p>15 And so it was nice to think I'd be able to skate</p> <p>16 and do all these other things, which I've never</p> <p>17 been able to do before, but what I was seeing was</p> <p>18 an enormous -- on the basis of this (indicating),</p> <p>19 perhaps, and others, I was seeing a tremendous</p> <p>20 amount of publicity and sales, in fact. And I</p> <p>21 remembered that particularly afterwards when</p> <p>22 there seemed to be problems with the -- with what</p> <p>23 we published because --</p> <p>24 Q When you say "sales" --</p>	<p>36</p> <p>1 Q And who are they?</p> <p>2 A Dr. DeAngelis and myself.</p> <p>3 Q All right, we're going to go through a</p> <p>4 lot of documents. So you can put that one to the</p> <p>5 side, but I'd like you to keep out Exhibit 3,</p> <p>6 which is the JAMA article because we're going to</p> <p>7 keep going back to that one, okay?</p> <p>8 I'd like to ask the court reporter to</p> <p>9 mark what will be Exhibit 45.</p> <p>10 (Deposition Exhibit No. 45</p> <p>11 was marked for ID)</p> <p>12 MR. MONTGOMERY: For the record, Exhibit 45</p> <p>13 is an article from the Global News Wire dated</p> <p>14 December 9th, 2005, specifically it's a</p> <p>15 transcript -- purports to be a transcript of an</p> <p>16 interview between Maria Bartiromo, yourself and</p> <p>17 another individual.</p> <p>18 BY MR. MONTGOMERY:</p> <p>19 Q Now, Dr. Rennie, I'm going to be</p> <p>20 giving you a lot of documents today to look</p> <p>21 through. And you're entitled to read every word</p> <p>22 of every page if you want to, but it may move</p> <p>23 things along if I just point you to the parts</p> <p>24 that I want to talk about; and then if you feel</p>

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<p>37</p> <p>1 you need more context, you can read the whole 2 thing.</p> <p>3 In this particular document, I'm only 4 going to ask you about your quotes -- well, first 5 I'm going to ask you about your quote in the 6 third paragraph of this document. So if you 7 could take a moment and read through that?</p> <p>8 A (Witness so doing).</p> <p>9 Q Okay, I'd like to direct you to your 10 quote in the third paragraph. First of all, do 11 you recall this interview?</p> <p>12 A Yes.</p> <p>13 Q Okay. I'd like to read part of your 14 quote into the record. It says, "While editors 15 depend on the researchers not lying to them, and 16 that's exactly what they did to the New York -- 17 I'm sorry, "the New England Journal of Medicine 18 and that's exactly what the some authors dealing 19 with the paper on Celebrex did to JAMA five years 20 ago." Do you see that?</p> <p>21 A Yes.</p> <p>22 Q And as far as you know, is that a 23 correct quote?</p> <p>24 A Yes.</p>	<p>39</p> <p>1 because the authors believed the six-month data 2 were the most scientifically and clinically 3 valid. The data after six months were so 4 confounded as to be difficult to interpret for 5 assessing a drug-related causal GI toxicity."</p> <p>6 Q So to be clear, is it correct to say 7 that you believed that the authors of the JAMA 8 article had lied to JAMA because they had only 9 presented six months of the class study instead 10 of a longer dataset?</p> <p>11 A Yes.</p> <p>12 Q Why do you believe that that was 13 deceptive?</p> <p>14 A Because, as I recollect, they -- there 15 were actually two studies that were amalgamated, 16 and that wasn't made clear. The one clear -- one 17 study, again, as I recollect, was twelve months 18 and the other was whatever it is, fourteen 19 months, something like that. The figure I have 20 in my mind is 65 weeks or something. And above 21 all, they had the results in their pockets.</p> <p>22 Now, it isn't straight dealing.</p> <p>23 Science operates -- cannot operate with police in 24 the lab. It can't be done. There has to be</p>
<p>38</p> <p>1 Q And the paper on Celebrex that you 2 referred to, is that the JAMA article --</p> <p>3 A Yeah.</p> <p>4 Q -- we've been discussing?</p> <p>5 A I guess I got the date wrong, didn't 6 I?</p> <p>7 Q But as far as -- it is the JAMA 8 article that you were referring to?</p> <p>9 A Yes.</p> <p>10 Q Do you still agree with that 11 statement?</p> <p>12 A Yes.</p> <p>13 Q And why did you believe that the 14 authors of the JAMA article had lied to JAMA?</p> <p>15 A Because they knew otherwise. In other 16 words, as was revealed, I think, in the letter 17 that they -- we published -- again, I had no hand 18 in this -- they said, "In retrospect, we 19 acknowledge that we could have avoided 20 confusing -- confusion by explaining to the JAMA 21 editors why we chose to inform them only of the 22 six-month analyses and not the longer term data 23 that were available to us when we submitted the 24 manuscript. We submitted only this information</p>	<p>40</p> <p>1 trust, and there has to be trust amongst 2 scientists and scientists with journals.</p> <p>3 And so you expect straight dealing, 4 and this wasn't straight dealing. They knew 5 results, which could be interpreted by others as 6 showing no effect, and those were not revealed.</p> <p>7 The editors weren't even given the 8 chance of saying -- apparently, weren't given the 9 chance of saying, Yes, we agree with you, these 10 are uninterpretable. They were treated as 11 idiots, and that's what that letter says.</p> <p>12 Q As a general matter, do most clinical 13 studies produce an array of datapoints?</p> <p>14 A Yes.</p> <p>15 Q And, typically, all of those 16 datapoints aren't presented along with every 17 article; is that correct?</p> <p>18 A Yes.</p> <p>19 Q And that isn't necessarily improper; 20 is that right?</p> <p>21 A Definitely not.</p> <p>22 Q So what was it about the specific data 23 that was not disclosed in this case in the JAMA 24 article that you found to be deceptive?</p>

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<p>41</p> <p>1 A I found it deceptive -- and, again, I</p> <p>2 did not handle this. All of this happened before</p> <p>3 I knew, okay?</p> <p>4 But what I found particularly</p> <p>5 distasteful was something that had re -- it</p> <p>6 reminded me of that had happened in 1978 when I</p> <p>7 was at Harvard and the Deputy Editor of New</p> <p>8 England Journal, and that was when two authors</p> <p>9 submitted and published on the same day in two</p> <p>10 different journals, one of them being JAMA -- one</p> <p>11 of them being the New England Journal results,</p> <p>12 which were completely contradictory.</p> <p>13 And their excuse was, yes, they knew</p> <p>14 the other results, but they didn't like to refer</p> <p>15 to unpublished work in a published work, which on</p> <p>16 the face of it is, of course, ludicrous and</p> <p>17 disingenuous.</p> <p>18 Now, I'm just try -- you asked me</p> <p>19 about my reaction here. And other editors were</p> <p>20 more vocal, perhaps, about it then I was, but I</p> <p>21 felt that if you don't give people a chance to</p> <p>22 see basic results, like -- basic facts of the</p> <p>23 design such as how many trials were there and how</p> <p>24 long did they last and what were they designed</p>	<p>43</p> <p>1 fundamental that if you design a study that's</p> <p>2 designed to do certain things, a whole lot of</p> <p>3 statisticians and clinicians get together and</p> <p>4 design a study, then you don't chop and change</p> <p>5 with it en route because you change all sorts of</p> <p>6 aspects about it including its statistical</p> <p>7 credibility if you do that.</p> <p>8 So those are two answers, a clinical</p> <p>9 one and a meaning answer.</p> <p>10 Q Are you familiar with the statistical</p> <p>11 term "type one error"?</p> <p>12 A Yeah.</p> <p>13 Q Okay.</p> <p>14 A Well, yes, but I'm not a statistician,</p> <p>15 and I emphasize I am not a statistician. I</p> <p>16 definitely am not.</p> <p>17 Q Are you -- do you have an</p> <p>18 understanding of type two error as well?</p> <p>19 A I think so.</p> <p>20 Q And --</p> <p>21 A But I'm not going to enlarge on that.</p> <p>22 Q All right, going back to Exhibit 45,</p> <p>23 would you please look at the second page?</p> <p>24 A (Witness so doing).</p>
<p>42</p> <p>1 for and how -- what was that design -- those are</p> <p>2 basic things -- then you are being deceptive.</p> <p>3 Q I don't want to put words in your</p> <p>4 mouth. I just want to try and condense that.</p> <p>5 So would it be fair to say that you</p> <p>6 found the specific data that was omitted from the</p> <p>7 JAMA article to be deceptive because it was so</p> <p>8 fundamental to the article?</p> <p>9 A Yes.</p> <p>10 Q And is one of the pieces of</p> <p>11 information we were just referring to the length</p> <p>12 of the study that was fundamental?</p> <p>13 A Yes.</p> <p>14 Q And why is that fundamental in your</p> <p>15 opinion?</p> <p>16 A Well, it's a general rule that --</p> <p>17 well, it's fundamental for quite a few reasons.</p> <p>18 You might take, for example, the fact that</p> <p>19 celecoxib, Celebrex, is a drug that's going to be</p> <p>20 used by elderly fold like me who climb too much</p> <p>21 for life. So one year is better than six months.</p> <p>22 Five years is going to be better than six months</p> <p>23 too.</p> <p>24 So that's one aspect to it, but it's</p>	<p>44</p> <p>1 Q In the second full paragraph, there's</p> <p>2 a quote by you I'm going to read into the record.</p> <p>3 It says, "That may be so, but the fact is that we</p> <p>4 have these cases, for example, the class study,</p> <p>5 for example, the bigger study about which the</p> <p>6 present fuss is going on, where journals were</p> <p>7 very directly lied to and misled." Do you see</p> <p>8 that?</p> <p>9 A Yes.</p> <p>10 Q And as far as you know, is that a</p> <p>11 correct quote?</p> <p>12 A No.</p> <p>13 Q Well, what is wrong with it?</p> <p>14 A "Bigger" should be "VIGOR" --</p> <p>15 Q Ah.</p> <p>16 A -- V-I-G-O-R. That concerned</p> <p>17 rofecoxib or Vioxx.</p> <p>18 Q Other than that change, is it a</p> <p>19 correct quote?</p> <p>20 A I imagine. This was a very trying</p> <p>21 interview because -- well, it doesn't matter</p> <p>22 whether it was trying or not, does it?</p> <p>23 Q Do you still agree with the statement</p> <p>24 that I just read into the record with the</p>

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<p>45</p> <p>1 correction that you made?</p> <p>2 A Yes.</p> <p>3 Q And --</p> <p>4 A Yes.</p> <p>5 Q -- when you say, "where journals were</p> <p>6 very directly lied to and misled," were you</p> <p>7 referring by example to the authors of the JAMA</p> <p>8 article lying to and misleading JAMA?</p> <p>9 A Yes. And the Advantage VIGOR and</p> <p>10 approve studies which had to do with rofecoxib or</p> <p>11 Vioxx. Actually -- well --</p> <p>12 Q Do you mean to say that you had an</p> <p>13 opinion that the authors of an article about that</p> <p>14 study had also lied to --</p> <p>15 A No.</p> <p>16 Q I'm sorry, let me just finish.</p> <p>17 (Continuing) -- to some journal? Go ahead.</p> <p>18 A Mr. Montgomery, I'm so sorry, I</p> <p>19 interrupted you. Would you mind asking your</p> <p>20 question again?</p> <p>21 Q Sure. I'm just trying to understand</p> <p>22 the relevance of VIGOR as you were just</p> <p>23 explaining it in your quote here as distinct from</p> <p>24 the quote that you made on the previous page.</p>	<p>47</p> <p>1 court reporter to mark what will be Exhibit 46.</p> <p>2 (Deposition Exhibit No. 46</p> <p>3 was marked for ID)</p> <p>4 THE VIDEOGRAPHER: If I could just switch</p> <p>5 tapes here?</p> <p>6 MR. NELSON: All right, why don't we take</p> <p>7 five minutes?</p> <p>8 MR. MONTGOMERY: Sure.</p> <p>9 THE VIDEOGRAPHER: This is the end of</p> <p>10 Video 1. The time is 2:33 p.m. The running time</p> <p>11 of this tape is 58 minutes and 59 seconds.</p> <p>12 (Recess taken.)</p> <p>13 THE VIDEOGRAPHER: This is the start of</p> <p>14 Video No. 2. The time is 2:41 p.m.</p> <p>15 MR. MONTGOMERY: All right, for the record,</p> <p>16 Exhibit 46 is a transcript of an interview on ABC</p> <p>17 dated May 29th, 2002.</p> <p>18 BY MR. MONTGOMERY:</p> <p>19 Q It's -- I think it's right there</p> <p>20 (indicating). Now, I'm only going to ask you</p> <p>21 about a quote on Page 79 of the interview, but</p> <p>22 feel free to look through as much of it as you</p> <p>23 need.</p> <p>24 A On which page, 79?</p>
<p>46</p> <p>1 A I'm just saying that in both the class</p> <p>2 study and the VIGOR study, and indeed in the</p> <p>3 other ones, misrepresentations were made by the</p> <p>4 authors to the journals, but the important ones</p> <p>5 are the class and the VIGOR ones.</p> <p>6 Q All right, going back to the quote we</p> <p>7 just discussed on the second page of Exhibit 45,</p> <p>8 is the basis for your belief that JAMA was lied</p> <p>9 to and misled by the authors of the JAMA article</p> <p>10 the same as what you have already put on the</p> <p>11 record?</p> <p>12 A Cathy DeAngelis and the FDA (nodding).</p> <p>13 Q And what about them?</p> <p>14 A That's right, they have a basis for</p> <p>15 these conclusions.</p> <p>16 Q What I want to just clarify is you</p> <p>17 explained regarding your quote on the previous</p> <p>18 page why you believe that JAMA had been lied to.</p> <p>19 A Yes.</p> <p>20 Q And I want to confirm that your basis</p> <p>21 for the statement on the second page that JAMA</p> <p>22 had been lied to is the same?</p> <p>23 A Yes.</p> <p>24 MR. MONTGOMERY: Okay. I'd like to ask the</p>	<p>48</p> <p>1 Q 79.</p> <p>2 A Thank you.</p> <p>3 Q All right, do you recall this</p> <p>4 interview in general?</p> <p>5 A Yeah. Poor Peter Jennings.</p> <p>6 THE REPORTER: I'm sorry, what did you say?</p> <p>7 THE WITNESS: I'm sorry. I said, "Poor</p> <p>8 Peter Jennings."</p> <p>9 THE REPORTER: Okay, thank you.</p> <p>10 THE WITNESS: He was a nice guy.</p> <p>11 BY MR. MONTGOMERY:</p> <p>12 Q Would you look to the bottom of the</p> <p>13 page? It's the second-to-last quote from you</p> <p>14 starting, "If only the good news". Do you see</p> <p>15 that?</p> <p>16 A Yes.</p> <p>17 Q Okay, I'm going to read it into the</p> <p>18 record. It says, "If only the good news about a</p> <p>19 drug is published and never the bad news, then a</p> <p>20 false impression is given of the quality and</p> <p>21 effectiveness of that drug. It may be entirely</p> <p>22 false." As far as you know, is that a correct</p> <p>23 quote?</p> <p>24 A Yes.</p>

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<p>49</p> <p>1 Q And do you still agree with that</p> <p>2 statement?</p> <p>3 A Yes.</p> <p>4 Q Do you believe that that is a fair</p> <p>5 characterization of the JAMA study at issue here?</p> <p>6 MR. HALPER: Objection to form.</p> <p>7 THE WITNESS: I'd like you to restate that</p> <p>8 question, because I never thought of it like</p> <p>9 that.</p> <p>10 BY MR. MONTGOMERY:</p> <p>11 Q Sure. All right, I'm going to be</p> <p>12 asking specifically about the JAMA article --</p> <p>13 A Yes.</p> <p>14 Q -- and I'll just take it one piece at</p> <p>15 a time here.</p> <p>16 A Yeah.</p> <p>17 Q The first part of your quote says, "If</p> <p>18 only the good news about a drug is published and</p> <p>19 never the bad news". So would it be fair to say</p> <p>20 in your estimation that the JAMA article included</p> <p>21 the good news, but did not include the bad news?</p> <p>22 MR. HALPER: Objection to form.</p> <p>23 THE WITNESS: I think it might hurry things</p> <p>24 up if I say that publication bias, which is the</p>	<p>51</p> <p>1 Q Do you have any reason to believe that</p> <p>2 it -- there's any incorrect data in the JAMA</p> <p>3 article?</p> <p>4 A I just don't know.</p> <p>5 Q All right, let's assume, if you will,</p> <p>6 that all of the data in the JAMA article is</p> <p>7 correct as presented.</p> <p>8 A (Nodding).</p> <p>9 Q Okay, given that assumption, would you</p> <p>10 still believe that the presentation was</p> <p>11 deceptive?</p> <p>12 A The issue here -- yes, because the</p> <p>13 issue has to do with the presentation of how long</p> <p>14 a study, how many studies and the full results --</p> <p>15 Q All right, let me --</p> <p>16 A -- or the fuller results.</p> <p>17 Q I don't mean to be repetitive, but let</p> <p>18 me just clarify.</p> <p>19 Why do you believe that the JAMA</p> <p>20 article would be deceptive even if all of the</p> <p>21 data it contains concerning six months was</p> <p>22 completely accurate?</p> <p>23 A Well, if a study went on for a year or</p> <p>24 whatever and it's represented that the entire</p>
<p>50</p> <p>1 tendency of authors to complete, researchers to</p> <p>2 complete and submit to journals and get published</p> <p>3 positive results, is a very serious matter that</p> <p>4 I've worried about since 1989 and have written on</p> <p>5 it, and it's very serious.</p> <p>6 But that is not what concerned me</p> <p>7 about this. This was a playing of trust and of</p> <p>8 plain speaking.</p> <p>9 BY MR. MONTGOMERY:</p> <p>10 Q Let's just talk about Exhibit 3 then</p> <p>11 more specifically.</p> <p>12 Is it correct to say that you've</p> <p>13 testified that in your opinion the presentation</p> <p>14 of data in the JAMA article -- I'm sorry.</p> <p>15 A Yeah.</p> <p>16 Q I'll wait for you to find it.</p> <p>17 A This is 3.</p> <p>18 Q All right. Is it -- in your opinion</p> <p>19 is the presentation of data in the JAMA article</p> <p>20 deceptive?</p> <p>21 A Yes.</p> <p>22 Q To your knowledge, is all of the data</p> <p>23 that's contained in the JAMA article correct?</p> <p>24 A I don't know.</p>	<p>52</p> <p>1 study is six months and there is other aspects</p> <p>2 how so, then that is in the nature of things</p> <p>3 deceptive.</p> <p>4 Now, there were other things too which</p> <p>5 I think are detailed in that second slide. Some</p> <p>6 of them, anyhow.</p> <p>7 Q I'd like to show the witness what's</p> <p>8 previously been marked as Exhibit 22.</p> <p>9 For the record, Exhibit 22 is an</p> <p>10 e-mail chain starting with an e-mail from Mona</p> <p>11 Wahba, W-A-H-B-A, to Stephen Cristo, C-R-I-S-T-O,</p> <p>12 dated May 22nd, 2001.</p> <p>13 Just let me know when you've had a</p> <p>14 chance to look through it.</p> <p>15 A Yeah.</p> <p>16 Q All right, do you recognize any of the</p> <p>17 names on this?</p> <p>18 A Yes.</p> <p>19 Q Which ones?</p> <p>20 A Well, Lefkowitz was one of the authors</p> <p>21 of the prior study, I'd have to go through them,</p> <p>22 wouldn't I?</p> <p>23 Q Yesm I'm actually looking for if you</p> <p>24 personally know any of the people.</p>

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<p>53</p> <p>1 A No.</p> <p>2 Q Okay.</p> <p>3 A No.</p> <p>4 Q All right, please take a look at the</p> <p>5 second page.</p> <p>6 A (Witness so doing).</p> <p>7 Q The first full email where it says,</p> <p>8 "Dear All," do you see that?</p> <p>9 A Yes.</p> <p>10 Q And you see it says "Please find</p> <p>11 attached two draft CLASS manuscripts (GI and CV)</p> <p>12 from Jim Lefkowitz's group." Do you see that?</p> <p>13 A Yes.</p> <p>14 Q All right, now, I'd like to direct you</p> <p>15 to the first page. See the first full email</p> <p>16 there that starts with "Dear All"?</p> <p>17 A Yes.</p> <p>18 Q And there's a quote, it says, in the</p> <p>19 second paragraph, second sentence, "We are also</p> <p>20 cherry picking the data (using six months as --</p> <p>21 6 m as a study duration)." Do you see that?</p> <p>22 A Yes.</p> <p>23 Q Did you see it?</p> <p>24 A Yes.</p>	<p>55</p> <p>1 has to be done all the time. That's science.</p> <p>2 You have to make judgments, but cherry picking is</p> <p>3 rather easier to judge in a trial than most</p> <p>4 because doing a trial is exceedingly expensive,</p> <p>5 very tedious, an enormous undertaking, and I have</p> <p>6 huge sympathy with the pharmaceutical companies</p> <p>7 that have to undertake this, huge. It's very</p> <p>8 difficult to accomplish that task.</p> <p>9 But the rules were laid out in 1948 by</p> <p>10 four people, still alive -- well, one died at 106</p> <p>11 the other day. The rules for doing a blinded,</p> <p>12 randomized clinical trial were laid out and have</p> <p>13 been refined since, but there's no Nobel Prize</p> <p>14 waiting for anyone who does a good clinical</p> <p>15 trial.</p> <p>16 It's all -- there are books about how</p> <p>17 to do it, and what -- and so selecting data in a</p> <p>18 clinical trial, you can decide beforehand what</p> <p>19 you're going to select, for example, and you've</p> <p>20 got to be exceedingly careful not to select the</p> <p>21 data in a selective way, positively way. And</p> <p>22 it's very difficult. You have to abandon all</p> <p>23 your feelings. It's very difficult. Boy,</p> <p>24 that's -- hum.</p>
<p>54</p> <p>1 Q Okay. Have you heard the term "cherry</p> <p>2 picking" in the context of medical studies</p> <p>3 before?</p> <p>4 A Yes.</p> <p>5 Q And do you have a general</p> <p>6 understanding of what it refers to?</p> <p>7 A Yes.</p> <p>8 Q And, generally speaking, what do you</p> <p>9 understand it to mean?</p> <p>10 A Well, it's what you're told not to do.</p> <p>11 If you -- you're strongly inclined to find one</p> <p>12 answer, then you pick those patients, those</p> <p>13 points that select that answer. You drop or</p> <p>14 don't drop outliers, you -- et cetera. You</p> <p>15 choose. You cherry pick.</p> <p>16 Q And is that improper scientific</p> <p>17 contact -- conduct, to cherry pick?</p> <p>18 A I think it's rather like a phrase,</p> <p>19 "with all due respect". If the term all due</p> <p>20 respect is used, it can mean with due respect,</p> <p>21 but we all know when people say "with all due</p> <p>22 respect", they mean no respect whatsoever, you</p> <p>23 see.</p> <p>24 So cherry picking, selection of data</p>	<p>56</p> <p>1 Q So is it your understanding that the</p> <p>2 rules regarding the conduct of clinical trials</p> <p>3 prohibit the cherry picking of data?</p> <p>4 A Well, it's, as I said with all due</p> <p>5 respect, cherry picking of the nature, if you use</p> <p>6 the word "cherry picking", you're using it in a</p> <p>7 derogatory fashion. You're saying this was --</p> <p>8 this selection was improper.</p> <p>9 Q So that I mean --</p> <p>10 A That's what you're saying.</p> <p>11 Q So that, by definition, would cherry</p> <p>12 picking the data be improper?</p> <p>13 MR. HALPER: Objection to form.</p> <p>14 THE WITNESS: By nature of -- by the -- the</p> <p>15 use of the term says it's improper, I would have</p> <p>16 thought, but, obviously, at this point that I'm</p> <p>17 not a linguist, etymologist, whatever the hell I</p> <p>18 am not supposed to be --</p> <p>19 BY MR. MONTGOMERY:</p> <p>20 Q All right, just to clarify, I'm only</p> <p>21 asking your understanding of the term --</p> <p>22 A Yes.</p> <p>23 Q -- to the best of your ability.</p> <p>24 A I've never heard the term cherry</p>

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<p>57</p> <p>1 picking used in an admirable way in statistics or 2 anything else. 3 Q All right, having read the JAMA 4 article, did -- did it disclose that the authors 5 were cherry picking the data was presented in 6 that article? 7 MR. HALPER: Objection to form. 8 THE WITNESS: I'd answer that by saying 9 they chose to disclose the six-month data. I 10 think that's something slightly different than 11 what I would call cherry picking, but I grew up a 12 physiologist doing a different type of research 13 in general, though I have published a randomized 14 clinical trial, at least one. I don't know if 15 I've done more. 16 BY MR. MONTGOMERY: 17 Q Just to clarify your answer there, did 18 you mean to say that it's your understanding that 19 the JAMA article disclo -- actually, can you read 20 his response back? 21 THE REPORTER: Sure. 22 (Record read.) 23 BY MR. MONTGOMERY: 24 Q All right, so what you were describing</p>	<p>59</p> <p>1 right-hand corner is -- ends 477. It's a Bates 2 number we refer to those as just in case -- all 3 right, I'd like you to look at the third full 4 paragraph that starts with "a bit of data 5 massage". 6 Okay, I'll read it into the record. 7 "With a bit of data massage, what Steve Geis and 8 his team have done is to focus on the 6 month 9 data, for no other reason than that it happens to 10 look better, and this time they concentrate on 11 the non-aspirin treated patients, and ignore the 12 fact that at no time interval did we see a 13 statistically significant difference with 14 diclofenac, whether one looks at patients taking 15 aspirin or not, at 6 or at 12 months." 16 Have you ever seen this document 17 before? 18 A No. 19 Q Okay. Let's start with the phrase 20 "data massage". Have you heard that phrase used 21 in the context of clinical studies before? 22 A Yes. 23 Q And do you have a general 24 understanding of what it means?</p>
<p>58</p> <p>1 there, to be clear, were you saying that's what 2 the JAMA article was saying, that it was 3 presenting certain data as opposed to cherry 4 picking or were you saying in your opinion there 5 was no cherry picking? 6 MR. HALPER: Objection. 7 THE WITNESS: I'm not saying anything about 8 cherry picking. It refers to something slightly 9 different, I believe. That's my interpretation 10 of this term. That's what I'm saying. 11 BY MR. MONTGOMERY: 12 Q Okay, I'd like to show the witness 13 what's previously been marked as Exhibit 28. 14 All right, once again, you can read as 15 much of this document as you want, but I'm only 16 going to ask you about one paragraph on the third 17 page. 18 A (Witness reviewing document). 19 Q Well, if -- you can write on it if you 20 want, but we'll just have to mark it -- or we'll 21 just have to say for the record to make it clear 22 that it wasn't there originally. 23 All right, I'd like you to look at the 24 third page of Exhibit 28. That number in the</p>	<p>60</p> <p>1 MR. HALPER: Objection to the form. 2 THE WITNESS: Yes. 3 BY MR. MONTGOMERY: 4 Q Generally speaking, what's your 5 understanding of the term? 6 A It comes under the same category, of 7 course, as cherry picking. It means -- well, a 8 statistician -- I've already said I'm not one -- 9 might say, If you torture data enough, you can 10 get something out of it. 11 And massaging the data sometimes means 12 leaving things out, saying that's irrelevant 13 and -- or using a different -- an inappropriate 14 statistical test or selecting, well, we'll miss 15 out the first month because everyone was getting 16 used to the pill and whether it's 17 the -- that sort of thing. It's thought to be a 18 bad -- it is bad. 19 Q Would it be a fair characterization to 20 call -- define data massage as analyzing data in 21 order to reach a predetermined conclusion? 22 A It tends to be that. That's what I 23 would think. I haven't looked that up. You 24 know, I'm sure it's in a phrase book somewhere.</p>

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<p>61</p> <p>1 Q All right, now I'd like to look at the</p> <p>2 part of the quote that I read into the record</p> <p>3 which states that, "what Steve Geis has done is</p> <p>4 to focus on the 6 month data mfor no reason -- no</p> <p>5 other reason than it happens to look better."</p> <p>6 Do you see that part?</p> <p>7 A Yeah.</p> <p>8 Q Now, having read the JAMA article, as</p> <p>9 you have, to your knowledge, is that fact,</p> <p>10 assuming it to be true, disclosed in the JAMA</p> <p>11 article anywhere?</p> <p>12 MR. HALPER: Objection. Objection to form,</p> <p>13 and I think it calls for speculation, but --</p> <p>14 MR. MONTGOMERY: All right, I'll rephrase</p> <p>15 the question, actually.</p> <p>16 BY MR. MONTGOMERY:</p> <p>17 Q Having read the JAMA article, to your</p> <p>18 knowledge, is that fact, that Steve Geis and his</p> <p>19 team focused on the six month data, for no other</p> <p>20 reason than it happens to look better, disclosed</p> <p>21 in the JAMA article anywhere?</p> <p>22 MR. HALPER: Objection to the term "fact".</p> <p>23 THE WITNESS: I don't believe so.</p> <p>24 MR. MONTGOMERY: I'd like to ask the witness</p>	<p>63</p> <p>1 Q All right, looking at Exhibit 4, have</p> <p>2 you seen this before?</p> <p>3 A Yes.</p> <p>4 Q And is this an editorial that was</p> <p>5 published, along with what we've been calling the</p> <p>6 JAMA article, in the September 13th, 2000 issue</p> <p>7 of JAMA?</p> <p>8 A Yes. I'd forgotten that Lichtenstein</p> <p>9 was a co-author. So it's years since I read it,</p> <p>10 but I read it when it came out at my office at</p> <p>11 BU, Boston, I think, as I remember.</p> <p>12 Q I would like to direct you to just one</p> <p>13 sentence in this editorial. It's on the second</p> <p>14 column of the first page, the first full</p> <p>15 paragraph that starts "Previous studies". Do you</p> <p>16 see that paragraph?</p> <p>17 A Yes.</p> <p>18 Q All right, in the middle of that</p> <p>19 paragraph, there's a description of the class</p> <p>20 study. It starts, "In this issue". Do you see</p> <p>21 that?</p> <p>22 A Yeah.</p> <p>23 Q All right, I'll read that into the</p> <p>24 record. It says, "In this issue of THE JOURNAL,</p>
<p>62</p> <p>1 to look at what's previously been marked as</p> <p>2 Exhibit 4.</p> <p>3 MR. NELSON: Thank you.</p> <p>4 MR. MONTGOMERY: Oh, wait. I'm sorry, I</p> <p>5 have the wrong -- can we go off the record for a</p> <p>6 minute?</p> <p>7 (Discussion off the record.)</p> <p>8 MR. MONTGOMERY: Back on the record.</p> <p>9 THE VIDEOGRAPHER: Recording.</p> <p>10 MR. MONTGOMERY: At this time, I would like</p> <p>11 to ask the court reporter to mark what will be --</p> <p>12 what has previously been marked as Exhibit 4, and</p> <p>13 I would like to thank defense counsel for</p> <p>14 generously sharing their copies.</p> <p>15 THE WITNESS: Thank you.</p> <p>16 MR. MONTGOMERY: For the record, Exhibit 4</p> <p>17 is an editorial published in the September 13th,</p> <p>18 2000 issue of JAMA entitled, "COX-2-Selective</p> <p>19 NSAIDs New and Improved?"</p> <p>20 BY MR. MONTGOMERY:</p> <p>21 Q Is it your understanding sitting here</p> <p>22 today that the class trials, as you've described</p> <p>23 them, lasted twelve months or longer?</p> <p>24 A Yes.</p>	<p>64</p> <p>1 Silverstein et. al. report the results of a</p> <p>2 6-month randomized, double-blind, controlled</p> <p>3 trial comparing the ulcerogenic potential and</p> <p>4 upper GI toxicity of celecoxib in individuals</p> <p>5 with osteoarthritis (OA) or rheumatoid arthritis</p> <p>6 (RA)." Do you see that?</p> <p>7 A Yes.</p> <p>8 Q Is it your understanding that is an</p> <p>9 incorrect description of the class trial?</p> <p>10 A Oh, yes.</p> <p>11 Q And would it be fair to say in your</p> <p>12 opinion that's a false --</p> <p>13 A It's a --</p> <p>14 Q I'm sorry?</p> <p>15 A It's a correct description of the</p> <p>16 reported -- of the report. It's incorrect</p> <p>17 description of what went on.</p> <p>18 Q Would it be fair to say that that's --</p> <p>19 that statement -- that description of the class</p> <p>20 trial that I just read into the record was false?</p> <p>21 A Yes.</p> <p>22 MR. MONTGOMERY: I'd like the court reporter</p> <p>23 to mark what will be Exhibit 47.</p> <p>24</p>



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<p>65</p> <p>1 (Deposition Exhibit No. 47</p> <p>2 was marked for ID)</p> <p>3 BY MR. MONTGOMERY:</p> <p>4 Q Once again, you can read as much as</p> <p>5 you want. I'm only going to ask you about the</p> <p>6 quote from you at the bottom of the first page</p> <p>7 that goes on to the top of the second page.</p> <p>8 For the record, Exhibit 47 is an</p> <p>9 article from Business Week dated June 24th, 2002</p> <p>10 with a headline "The Credibility Gap in Drug</p> <p>11 Research."</p> <p>12 A Yes.</p> <p>13 Q All right, I'd like to read part of</p> <p>14 that into the record starting on the bottom of</p> <p>15 the first page. It says, "The studies authors,</p> <p>16 including Pharmacia 'were not open with us' -- I</p> <p>17 got to restart that. Strike what I just said.</p> <p>18 I'm going to read part of the article</p> <p>19 into the record. It says, "The study's authors,</p> <p>20 including Pharmacia, 'were not open with us,' he</p> <p>21 says. 'They signed letters saying the studies</p> <p>22 had all the relevant stuff,' but 'they had</p> <p>23 contradictory results when they sent us this</p> <p>24 paper, and they should have revealed them to</p>	<p>67</p> <p>1 in that quote?</p> <p>2 A Yeah.</p> <p>3 Q All right, turning --</p> <p>4 A However --</p> <p>5 Q I'm sorry, go ahead.</p> <p>6 A No.</p> <p>7 Q All right. Turning to the second page</p> <p>8 where you say -- well, starting on the first</p> <p>9 page, "They had contradictory results when they</p> <p>10 sent us this paper, and they should have revealed</p> <p>11 them to us" --</p> <p>12 A Um-hum.</p> <p>13 Q Why did you believe that they should</p> <p>14 have revealed to you the contradictory results?</p> <p>15 A Well, for all the reasons that we've</p> <p>16 discussed. I'm a -- the only virtue of getting</p> <p>17 older is that you become a patient or if you</p> <p>18 bounce off a lot of cliffs, as I've done, and</p> <p>19 that gives you a different view, and you rather</p> <p>20 value the idea that the doctor's prescribing hand</p> <p>21 is guided by fact rather than fiction.</p> <p>22 Q And in this case, are you</p> <p>23 characterizing the JAMA article as fiction?</p> <p>24 A No, I was saying I don't think it is</p>
<p>66</p> <p>1 us." "I'm sorry, "And they didn't." Do you</p> <p>2 see that?</p> <p>3 A Yes.</p> <p>4 Q Is the quote from you contained in</p> <p>5 that excerpt correct?</p> <p>6 A I imagine. It sounds like me.</p> <p>7 Q Now, do you remember giving this</p> <p>8 interview?</p> <p>9 A I give a lot of interviews. I can't</p> <p>10 specifically remember this.</p> <p>11 Q The quote I just read into the record</p> <p>12 though, that sounds accurate to you?</p> <p>13 A Yeah.</p> <p>14 Q Okay, do you still agree with it?</p> <p>15 A Yes.</p> <p>16 Q Where you say, "They signed letters</p> <p>17 saying the studies have all the relevant stuff,"</p> <p>18 what are you referring to?</p> <p>19 A We have letters -- they keep changing</p> <p>20 now, but that we haven't sent stuff elsewhere,</p> <p>21 we're sending you all the relevant stuff, and so</p> <p>22 on. I don't have them in front of me now, but</p> <p>23 that's certainly what we used to do.</p> <p>24 Q And that's what you were referring to</p>	<p>68</p> <p>1 fiction. I think it's partial truth.</p> <p>2 Q All right, at this time, I'd like to</p> <p>3 ask the witness to look at what's previously been</p> <p>4 marked as Exhibit 36.</p> <p>5 Before we move on to 36, I just want</p> <p>6 to -- I can't recall whether I asked you -- the</p> <p>7 quote I read into the record from you from</p> <p>8 Exhibit 47, do you still agree with everything</p> <p>9 you said there?</p> <p>10 A Yes.</p> <p>11 Q Okay.</p> <p>12 A And including the -- I'm asking here.</p> <p>13 Are we talking about the next paragraph as well?</p> <p>14 Q No, just the part I read into the</p> <p>15 record.</p> <p>16 A Just the part, yes, because that --</p> <p>17 yeah. Thank you.</p> <p>18 Q Have you seen Exhibit 36 before --</p> <p>19 A Yeah.</p> <p>20 Q -- or a copy of that?</p> <p>21 A Yeah.</p> <p>22 Q And what is it?</p> <p>23 A It's the -- the authorship criteria,</p> <p>24 the "Authorship Criteria and Responsibility,</p>

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<p>69</p> <p>1 Financial Disclosure, Copyright Transfer, and 2 Acknowledgment" as of the end of August 2001. 3 So just before this paper came in, 4 which is what you're talking about, or before it 5 was published, though I don't know whether it 6 was -- whether it was the same, earlier that 7 year. 8 Q All right, actually -- 9 A Because this is a developing document. 10 I'm just being cautious here. 11 Q Sure. I'd like to point out the date 12 is actually -- at the lower right-hand corner is 13 actually after the JAMA article was published. 14 A Oh, I'm sorry. January 2001, of 15 course. 16 Q Yes. 17 A I'm sorry. 18 Q That's okay. All right, there's 19 different sections to this document I'd like to 20 talk about. The first section entitled, 21 "Authorship Responsibility, Criteria, and 22 Contributions", do you see that? 23 A Yes. 24 Q Do you have an understanding of what</p>	<p>71</p> <p>1 a disclosure such as Exhibit 36 or something 2 substantially similar? 3 A I have no idea, but I -- I don't know. 4 Q Let me ask it a different way. As of 5 2000, were the authors of articles published in 6 JAMA required to sign disclosures similar to 7 Exhibit 36? 8 A Yes. I wasn't being cute. I've seen 9 all authorsh -- one person sign all the 10 signatures. I've seen the editorial system 11 break down. That's my understanding. 12 Q Do you believe that as of 2000 -- 13 well, scratch that question. 14 Is it correct to say that, as you 15 testified before, you have some understanding of 16 what clinicians who read JAMA expect of the 17 articles that are published in it? 18 MR. HALPER: Objection to form. 19 THE WITNESS: Yeah. 20 BY MR. MONTGOMERY: 21 Q All right, with regard to authorship, 22 do you believe that the clinicians who read JAMA 23 in general have an understanding that everyone 24 listed as an author in an article published in</p>
<p>70</p> <p>1 that -- the purpose of that section is? 2 A I should have. They're there 3 before -- because of me. 4 Q All right, what is the purpose of that 5 section? 6 A Not entirely because of me, but the 7 idea is to have people stand up behind what they 8 publish. 9 It was my experience at the New 10 England Journal and then initially at JAMA was 11 things happened after publication of a 12 document -- of an article. The press conference 13 was held, lots of credit. When blame came, no 14 one around, lots of pointing of fingers, Not me, 15 everyone else's fault. 16 The idea is to just remind people of 17 their responsibilities. It's what lawyers call 18 notice, right? But all it is saying is these are 19 the -- it's drawing attention to the some of the 20 norms of science, that's all. 21 Is this degrading, as I was once 22 asked? Yes. It's pathetic we have to do this. 23 Q And is it your understanding that each 24 of the authors of the JAMA article either signed</p>	<p>72</p> <p>1 JAMA meets more or less the criteria set forth in 2 Exhibit 36? 3 MR. HALPER: Objection, calls for 4 speculation. 5 THE WITNESS: I just don't know. I would 6 hope so. 7 MR. MONTGOMERY: I'd like to ask the court 8 reporter to mark what will be Exhibit 48. 9 (Deposition Exhibit No. 48 10 was marked for ID) 11 MR. MONTGOMERY: For the record, Exhibit 48 12 is an article from the Wall Street Journal Asia 13 dated May 19th, 2004, headline, "Merck Takes 14 Author's Name Off Vioxx Study." Vioxx has two 15 Xs. 16 BY MR. MONTGOMERY: 17 Q All right, and I'm only going to ask 18 you about the -- your quote in the fourth full 19 paragraph starting "Throughout". 20 Okay, the quote I'm looking at at the 21 bottom of that paragraph says, "If the people up 22 there in the list of authors aren't responsible 23 for everything in the article, something's wrong. 24 It's completely unethical." Do you see that?</p>

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<p>73</p> <p>1 A Yes.</p> <p>2 Q Does that appear to be an accurate</p> <p>3 quote?</p> <p>4 A Very much so.</p> <p>5 Q And do you still agree with it?</p> <p>6 A Very much so.</p> <p>7 Q When you said "the authors" -- when</p> <p>8 you refer to authors being responsible for</p> <p>9 everything in the article, did you mean as you</p> <p>10 said before, willing to take the blame if it's</p> <p>11 found to be defective?</p> <p>12 A Yes.</p> <p>13 Q Did you --</p> <p>14 A It --</p> <p>15 Q I'm sorry, I didn't mean to interrupt</p> <p>16 you?</p> <p>17 A It's apparent to me and to editors</p> <p>18 more and more that a disconnect seems to happen</p> <p>19 that's as I've told you.</p> <p>20 I invited a -- Josh Lederberg, who got</p> <p>21 the Nobel Prize for molecular biology, big</p> <p>22 discoveries, and I've asked him what he thought,</p> <p>23 and I got him to say -- I'm trying to get the</p> <p>24 words right, but they went like this:</p>	<p>75</p> <p>1 Q And why is it unethical in your</p> <p>2 opinion?</p> <p>3 A Well, because that person or these --</p> <p>4 those people who are responsible aren't there</p> <p>5 openly being responsible to the reader.</p> <p>6 And believe me, problems arise later</p> <p>7 often. And I'm not talking just misconduct,</p> <p>8 though that's one of them, but just questions</p> <p>9 about the science.</p> <p>10 Q Have you published any articles</p> <p>11 concerning the ethics of authorship in scientific</p> <p>12 articles?</p> <p>13 A Yes.</p> <p>14 Q Approximately how many?</p> <p>15 A A dozen.</p> <p>16 Q And where are --</p> <p>17 A But --</p> <p>18 Q I'm sorry.</p> <p>19 A -- some of them have been</p> <p>20 investigating what people do and things like</p> <p>21 that.</p> <p>22 Q And if somebody --</p> <p>23 A I suppose. I'm guessing. I don't</p> <p>24 know.</p>
<p>74</p> <p>1 "The manuscript submitted for</p> <p>2 publication is a testament under oath. That's</p> <p>3 how seriously a scientist should take what they</p> <p>4 write. It's their only product. It's what they</p> <p>5 make their fame on, fortune, everything else, is</p> <p>6 their -- their scientific article. It better be</p> <p>7 right. They have to stand behind it." And he</p> <p>8 said something that I profoundly believe.</p> <p>9 Q In addition to being willing to take</p> <p>10 responsibility if something's found to be wrong</p> <p>11 with an article, were you also referring to the</p> <p>12 idea that being listed as an author also means</p> <p>13 that you actually contributed to the content of</p> <p>14 whatever article is being published?</p> <p>15 A Yes. I've written several articles</p> <p>16 and done several studies on exactly that.</p> <p>17 Q And do you believe it's unethical for</p> <p>18 an individual to be listed as an author in a</p> <p>19 journal article who did not actually contribute</p> <p>20 to the contents of the article?</p> <p>21 A Yes. That's ghost authorship -- well,</p> <p>22 that's guest authorship usually, and ghost</p> <p>23 authorship is when the person who wrote it isn't</p> <p>24 there or up there. Another bad, bad, bad habit.</p>	<p>76</p> <p>1 Q I understand. I'm just looking for</p> <p>2 your best estimate.</p> <p>3 A Yes.</p> <p>4 Q Have some of those articles been</p> <p>5 printed in peer-reviewed journals?</p> <p>6 A Yes.</p> <p>7 Q Would you characterize the practice of</p> <p>8 guest writing, as you've described it, as</p> <p>9 deceptive?</p> <p>10 A It's a little sin, I suppose. It's</p> <p>11 naughty. It's not bad. Bad is when you --</p> <p>12 you're deceptive about your report. I think</p> <p>13 asking -- giving somebody a place on the line</p> <p>14 tends to produce terrible effects, but it's a</p> <p>15 little sin.</p> <p>16 Q Would you think -- would you</p> <p>17 characterize it as misleading?</p> <p>18 A Not in the same way as the -- what</p> <p>19 we've been talking about before.</p> <p>20 Q But --</p> <p>21 A Yes, it's misleading. Usually, it's</p> <p>22 putting some Puba like me on the line to give the</p> <p>23 thing credibility, which in my case, it doesn't.</p> <p>24 MR. MONTGOMERY: Does anybody need a break</p>

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<p>77</p> <p>1 or can we just keep moving forward?</p> <p>2 MR. NELSON: I'm okay as long as I can keep</p> <p>3 standing up.</p> <p>4 MR. MONTGOMERY: It's your building.</p> <p>5 MR. NELSON: Yeah.</p> <p>6 THE WITNESS: Well, as long as the building</p> <p>7 keeps standing up.</p> <p>8 THE VIDEOGRAPHER: The tape will be over in</p> <p>9 thirteen minutes if you want to use that as --</p> <p>10 MR. MONTGOMERY: Perfect. I would like to</p> <p>11 ask the court reporter to mark what will be</p> <p>12 Exhibit 49.</p> <p>13 (Deposition Exhibit No. 49</p> <p>14 was marked for ID)</p> <p>15 BY MR. MONTGOMERY:</p> <p>16 Q Have you seen Exhibit 49 before?</p> <p>17 A Yes, six years ago.</p> <p>18 Q Okay, is it a letter to you from a</p> <p>19 Jennifer -- I'm going to have to spell this. I</p> <p>20 have no idea how to say it.</p> <p>21 A Rocovec (phonetic).</p> <p>22 Q Rocovec, H-R-A-C-H-O-V-E-C. And is --</p> <p>23 did this letter also attach a manuscript or a</p> <p>24 Letter to the Editor for JAMA?</p>	<p>79</p> <p>1 a different exhibit, and we'll try to fix it. In</p> <p>2 the meantime, why don't you give that back to the</p> <p>3 court reporter, and she'll -- we'll find a copy</p> <p>4 that's got the right -- all the pages.</p> <p>5 THE WITNESS: Thank God for that. Is this</p> <p>6 (indicating) still on?</p> <p>7 MR. MONTGOMERY: Yes. All right --</p> <p>8 THE WITNESS: Well, I guess I'm speaking to</p> <p>9 the right person. I thought I'd gone nuts</p> <p>10 looking at that date.</p> <p>11 MR. MONTGOMERY: I apologize.</p> <p>12 THE WITNESS: As you saw, I was busy -- all</p> <p>13 right, continue.</p> <p>14 MR. MONTGOMERY: All right, I'd like to ask</p> <p>15 the court reporter to mark what will be</p> <p>16 Exhibit 50.</p> <p>17 (Deposition Exhibit No. 50</p> <p>18 was marked for ID)</p> <p>19 MR. MONTGOMERY: All right, for the record,</p> <p>20 Exhibit 50 is a Business Week article dated June</p> <p>21 28th, 2004 entitled "When Medicine and Money</p> <p>22 Don't Mix".</p> <p>23 BY MR. MONTGOMERY:</p> <p>24 Q I'm just going to ask you about your</p>
<p>78</p> <p>1 A Yeah.</p> <p>2 Q Do you know why this was sent to you</p> <p>3 in particular?</p> <p>4 A (Shaking head).</p> <p>5 Q Did you play any part in reviewing it?</p> <p>6 A No. I have no idea. I'm embarrassed</p> <p>7 that I'd forgotten about it. I handed it on to</p> <p>8 Letters, as I recollect. That's it. And it</p> <p>9 shows my memory defective.</p> <p>10 Q All right, I'd like to ask the witness</p> <p>11 to look at what's previously been marked as</p> <p>12 Exhibit 31.</p> <p>13 A (Witness so doing).</p> <p>14 MR. NELSON: You know, before you get too</p> <p>15 far into 31, you know it's missing a page? Just</p> <p>16 look at the Bates numbers.</p> <p>17 MR. HALPER: This is the same problem.</p> <p>18 MR. MONTGOMERY: It's the same problem we</p> <p>19 had before.</p> <p>20 MR. NELSON: Yeah.</p> <p>21 MR. MONTGOMERY: How much longer on the</p> <p>22 tape?</p> <p>23 THE VIDEOGRAPHER: About nine minutes.</p> <p>24 MR. MONTGOMERY: All right, let me go on to</p>	<p>80</p> <p>1 quote in the middle of the second page.</p> <p>2 A (Witness reviewing document).</p> <p>3 Q All right, I'm going to read into the</p> <p>4 record an excerpt, which is not all a quote from</p> <p>5 Dr. Rennie. It says, "It's impossible to know</p> <p>6 how prevalent ghost writing is. But Dr. Drummond</p> <p>7 Rennie, Professor of Medicine at the University</p> <p>8 of California San Francisco and Deputy Editor of</p> <p>9 the Journal of the American Medical Association</p> <p>10 believes it is 'pervasive, deceptive, and</p> <p>11 disgraceful.'"</p> <p>12 Does that appear to be an accurate</p> <p>13 quote to you?</p> <p>14 A Yes.</p> <p>15 Q Do you still agree with it?</p> <p>16 A Yes.</p> <p>17 Q Could you explain to me again what the</p> <p>18 difference is between ghost writing and guest</p> <p>19 writing in this context?</p> <p>20 A Let's do it backwards. A guest writer</p> <p>21 is when I, a junior, put Cathy DeAngelis's name</p> <p>22 on a paper and send it in with the hope that that</p> <p>23 paper will -- into a journal with the hope that</p> <p>24 that paper will be published more easily, more</p>

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<p style="text-align: right;">81</p> <p>1 quickly and get more attention simply because her 2 name is on it even if she did nothing and 3 sometimes without her knowledge, and it's been 4 the downfall of quite a lot of senior people 5 who've had fraudulent articles published in that 6 way with their names attached. 7 Now, ghost writing is the habit, 8 typically, of paying a contract research 9 organization, the people in it, to write papers 10 and then hand them on to the people whose names 11 are on the paper and without the name of the 12 person who actually wrote the thing. 13 There's one in this connection with 14 the Advantage study published in the Annals of 15 Internal Medicine. Dr. Liise -- this is on 16 Vioxx -- when interviewed by the New York Times 17 said something along the lines, "Merck is the 18 first author and the principal investigator." He 19 was -- the study was thought up, designed, 20 conducted, analyzed, the data collected, 21 analyzed, written up, and the paper in full form 22 sent to me to add my name to it. I didn't know 23 the patients who died, et cetera. That's ghost 24 writing because the person who wrote that paper</p>	<p style="text-align: right;">83</p> <p>1 A (Witness so doing). 2 Q On the first page, I'm actually just 3 going to ask you about something in the 4 "Guidelines For Letters" in the lower right-hand 5 corner. 6 A Yes. 7 Q All right, in the middle of that 8 paragraph, it says, "A signed statement for 9 authorship criteria and responsibility, financial 10 disclosure, copyright transfer, and 11 acknowledgment is required for publication." Do 12 you see that? 13 A Yes. 14 Q Does that mean that for a Letter to 15 the Editor to be published, the authors have to 16 sign a form substantially similar to what was 17 marked as Exhibit 36? 18 A Yes, I believe so. 19 Q And is it for the same reasons? 20 A Yes. 21 Q All right, would you turn to the 22 second page of Exhibit 31? 23 A (Witness so doing). 24 Q All right, at the top of the second</p>
<p style="text-align: right;">82</p> <p>1 nowhere appears on the list of authors, and 2 occasionally it comes out in that way. 3 Q And why do you believe that's 4 deceptive? 5 A Because there's no connection. If 6 anyone complains, the author -- the senior 7 authors, as happened in that particular case, 8 says, Don't blame me, I never knew any of the 9 patients, any of the data or anything. 10 MR. MONTGOMERY: All right, let's go off the 11 record. 12 THE VIDEOGRAPHER: This is the end of 13 Video 2. The time is 3:39 p.m. The running time 14 of this tape is 57 minutes and 48 seconds. 15 (Recess taken.) 16 THE VIDEOGRAPHER: This is the start of 17 Video No. 3. The time is 3:45 p.m. 18 BY MR. MONTGOMERY: 19 Q You understand you're still under 20 oath? 21 A Yes. 22 Q Okay, I'd like to ask the witness to 23 look at what's been previously marked as 24 Exhibit 31.</p>	<p style="text-align: right;">84</p> <p>1 column there, there's a sentence beginning, 2 "Fourth and most important". Do you see that? 3 A Yes. 4 Q I would like to read that into the 5 record. It says, "Fourth and most important, 6 after the blind was broken, it became clear that 7 there was a differential dropout rate of NSAID 8 patients with GI intolerance or symptomatic 9 ulcers, suggesting that those patients at 10 greatest risk were no longer in the study. This 11 type of informative censoring leads to a bias, 12 which potentially invalidates statistical 13 analysis of complicated ulcers by the log rank 14 test." Do you see that? 15 A Yes. 16 Q All right, I'd like to refer to that 17 theory, as it were, as "informative censoring" as 18 a sort of a shorthand. Is that all right with 19 you? 20 A Yes. 21 Q Do you have a general understanding of 22 what that -- I just read means? 23 A I think so. 24 Q Can you explain it to me in sort of</p>

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<p>85</p> <p>1 laymen's terms?</p> <p>2 MR. HALPER: Well, I just want to clarify.</p> <p>3 Are you asking for Dr. Rennie's understanding of</p> <p>4 informative censoring or what he thinks the</p> <p>5 authors meant when they used that term here?</p> <p>6 MR. MONTGOMERY: Sure, his understanding.</p> <p>7 MR. HALPER: Okay.</p> <p>8 THE WITNESS: You know, I think I'm going</p> <p>9 to get into trouble if I start giving -- giving</p> <p>10 definitions of statistical concepts, and as I've</p> <p>11 said before, I think it's a bad plan that I get</p> <p>12 into that.</p> <p>13 BY MR. MONTGOMERY:</p> <p>14 Q All right, and just in the most</p> <p>15 general laymen's terms, would it be fair to say</p> <p>16 that the informative censoring theory contends</p> <p>17 that the class study became more biased as time</p> <p>18 went on due to the dropout rates? Would you feel</p> <p>19 comfortable with that?</p> <p>20 MR. HALPER: Object to form.</p> <p>21 THE WITNESS: It might, but I don't think</p> <p>22 that's the point is what I'm saying.</p> <p>23 BY MR. MONTGOMERY:</p> <p>24 Q Sure. I'm just trying to talk about</p>	<p>87</p> <p>1 could make an informed judgment about that, and</p> <p>2 I'm not going to. Is that cooperative?</p> <p>3 BY MR. MONTGOMERY:</p> <p>4 Q Yes. I just want to make clear I'm</p> <p>5 not asking you for your opinion of the theory</p> <p>6 itself, the informative censoring --</p> <p>7 A Yes.</p> <p>8 Q -- whether you think it's valid or not</p> <p>9 valid, just whether you generally understand</p> <p>10 what -- what it is.</p> <p>11 A Well, I'm going to say no because I've</p> <p>12 seen it in different guises. So I'm going to say</p> <p>13 no.</p> <p>14 Q So the -- specifically the portion of</p> <p>15 the letter that I just read into the record, you</p> <p>16 don't have a general understanding of what that</p> <p>17 theory is?</p> <p>18 MR. HALPER: That's a different --</p> <p>19 THE WITNESS: That's different.</p> <p>20 MR. HALPER: You're asking now Dr. Rennie</p> <p>21 to talk about what the authors meant.</p> <p>22 MR. MONTGOMERY: No, no, I'm asking him --</p> <p>23 MR. HALPER: Oh.</p> <p>24 MR. MONTGOMERY: (Continuing) -- if he has</p>
<p>86</p> <p>1 the theory as it's posited by someone else. Is</p> <p>2 that enough or is that still not enough?</p> <p>3 A I'm not going to say.</p> <p>4 Q Okay. All right, the letter that</p> <p>5 that's contained in --</p> <p>6 MR. NELSON: Let me go --</p> <p>7 MR. MONTGOMERY: Sure.</p> <p>8 MR. NELSON: Can I just discuss this with</p> <p>9 the witness? I mean there's a problem when a</p> <p>10 witness says, I'm not going to say. But it may</p> <p>11 be we can clarify it, so let's just --</p> <p>12 MR. MONTGOMERY: Sure. Let's go off the</p> <p>13 record.</p> <p>14 MR. NELSON: Let's go outside for a second.</p> <p>15 (Recess taken.)</p> <p>16 THE VIDEOGRAPHER: Recording.</p> <p>17 MR. NELSON: All right, I've spoken with</p> <p>18 Dr. Rennie. He would like to clarify his last</p> <p>19 comment. So if you would, please?</p> <p>20 THE WITNESS: I don't want you to think I'm</p> <p>21 uncooperative. That's far from the case. I want</p> <p>22 to be as cooperative as I can.</p> <p>23 I don't want to make judgments based</p> <p>24 on an expertise that I know a hundred people</p>	<p>88</p> <p>1 an understanding of informative censoring as it's</p> <p>2 described there.</p> <p>3 MR. HALPER: Well, I'll object, and I think</p> <p>4 it calls for speculation.</p> <p>5 MR. NELSON: Well, I mean I think in</p> <p>6 fairness --</p> <p>7 MR. MONTGOMERY: Sure.</p> <p>8 MR. NELSON: The objection is well taken. I</p> <p>9 think that the earlier objection was, Do you mean</p> <p>10 A or do you mean B? And you said, I mean B, and</p> <p>11 now I think you're asking A again. And that's</p> <p>12 fine, it's your prerogative --</p> <p>13 MR. MONTGOMERY: Sure.</p> <p>14 MR. NELSON: (Continuing) -- but I just</p> <p>15 think you should make it clear that this is a new</p> <p>16 question you're asking.</p> <p>17 MR. MONTGOMERY: Okay, I don't think it is,</p> <p>18 but what I'm trying to say is there's a theory</p> <p>19 described here, we called it informative</p> <p>20 censoring, and I'm asking if he has an</p> <p>21 understanding, a general understanding of what</p> <p>22 that theory is.</p> <p>23 THE WITNESS: Well, I certainly understand</p> <p>24 what's being said here.</p>

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<p>89</p> <p>1 BY MR. MONTGOMERY:</p> <p>2 Q Okay.</p> <p>3 A I think that's really -- I don't know</p> <p>4 what it is you want.</p> <p>5 Q Okay.</p> <p>6 A I'm -- not want. What -- okay.</p> <p>7 Q All right, let's -- let's just move</p> <p>8 on. Actually, before we move on, the letter that</p> <p>9 we were just discussing and the quotation is from</p> <p>10 a letter by Fred Silverstein, Lee Simon and</p> <p>11 Gerald Faich; is that correct?</p> <p>12 A Yes.</p> <p>13 Q And did you have any role in reviewing</p> <p>14 that letter prior to publication?</p> <p>15 A No.</p> <p>16 Q All right, I'd like to ask the witness</p> <p>17 to look at what has previously been marked as</p> <p>18 Exhibit 24. And watch out, I actually ran out of</p> <p>19 staples in my room last night, so these are</p> <p>20 loose.</p> <p>21 For the record, Exhibit 24 is an</p> <p>22 e-mail string starting with an e-mail from Joy</p> <p>23 Dicker to Mona Wahba dated August 23rd, 2001.</p> <p>24 I'm only going to be asking you about</p>	<p>91</p> <p>1 see that?</p> <p>2 A Yes.</p> <p>3 Q And were -- to your knowledge, were</p> <p>4 Mr. Verburg -- or Dr. Verburg and Friedman listed</p> <p>5 as authors in the Letter to the Editor that was</p> <p>6 eventually published?</p> <p>7 A No. It would be Silverstein, Simon,</p> <p>8 Faich.</p> <p>9 Q Okay, and I'd like you to look at</p> <p>10 what's previously been marked Exhibit 39.</p> <p>11 A Thank you.</p> <p>12 Q For the record, Exhibit 39 is an</p> <p>13 e-mail string starting with an e-mail from Goran</p> <p>14 Ando, A-N-D-O, first name G-O-R-A-N, to Phillip</p> <p>15 Needleman and several others dated August 13th,</p> <p>16 2001.</p> <p>17 A Yes.</p> <p>18 Q The subject heading is "JAMA Letters</p> <p>19 to the Editor." If you would, I would like you</p> <p>20 to look at the first paragraph on the first page.</p> <p>21 A (Witness so doing).</p> <p>22 Q The third sentence reads, "Once we</p> <p>23 redraft the letter we would send it to the</p> <p>24 authors and get their buy-in with the intent of</p>
<p>90</p> <p>1 Item 4 on the second page. Have you had a chance</p> <p>2 to look at Exhibit 24?</p> <p>3 A Yes.</p> <p>4 Q Okay.</p> <p>5 A Well, part of it. I mean --</p> <p>6 Q Do you see that it concerns a</p> <p>7 meeting --</p> <p>8 A Yes.</p> <p>9 Q -- with Ken Verburg and Michael</p> <p>10 Friedman with Dr. DeAngelis?</p> <p>11 A Yes.</p> <p>12 Q And is Dr. DeAngelis the Editor in</p> <p>13 Chief of JAMA?</p> <p>14 A Yes.</p> <p>15 Q All right, would you turn to the</p> <p>16 second page, please?</p> <p>17 A (Witness so doing).</p> <p>18 Q I'd like to read Item 4 into the</p> <p>19 record. It says, "She provided some very useful</p> <p>20 advice concerning her expectations for our Letter</p> <p>21 to the Editor responding to criticism -----based</p> <p>22 on this advice Ken and I drafted a revision that</p> <p>23 is being reviewed and worked on Tuesday evening</p> <p>24 and will be circulated for approval." Do you</p>	<p>92</p> <p>1 making the 10 day timeline imposed by JAMA." Do</p> <p>2 you see that?</p> <p>3 A Um-hum.</p> <p>4 Q If that statement and the statement I</p> <p>5 just read to you out of Exhibit 24 are correct,</p> <p>6 does it appear to you that that letter was -- the</p> <p>7 letter that was published in JAMA was ghost</p> <p>8 written?</p> <p>9 MR. HALPER: Objection, foundation.</p> <p>10 THE WITNESS: Well, if they are correct,</p> <p>11 the people -- the person who wrote this</p> <p>12 (indicating) and negotiated with Dr. DeAngelis</p> <p>13 and Dr. Fontanarosa are at a meeting I knew</p> <p>14 nothing about until now, they weren't on -- on</p> <p>15 the letter.</p> <p>16 BY MR. MONTGOMERY:</p> <p>17 Q And is that ghost writing?</p> <p>18 MR. HALPER: Objection to form.</p> <p>19 THE WITNESS: You'd call it something like</p> <p>20 that.</p> <p>21 BY MR. MONTGOMERY:</p> <p>22 Q Would you call it something like that?</p> <p>23 A Yeah, but -- yes. Yes, I would. And</p> <p>24 I can understand it.</p>

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<p>93</p> <p>1 Q I'd like to ask the witness to look at</p> <p>2 what's previously been marked as Exhibit 27.</p> <p>3 A (Witness so doing).</p> <p>4 Q Now, I'm only going to ask you about</p> <p>5 the second-to-last page of this document, but</p> <p>6 you're free to look through it if you wish.</p> <p>7 A Yes.</p> <p>8 Q For the record, Exhibit 27 is an</p> <p>9 e-mail with attachments. The email is from</p> <p>10 Carolyn Wilson to George Geis and several other</p> <p>11 individuals dated March 20th, 2000.</p> <p>12 Just let me know when you get to the</p> <p>13 second-to-last page.</p> <p>14 A Well, I'm on the second-to-last</p> <p>15 page --</p> <p>16 Q So it should -- in the lower</p> <p>17 right-hand corner --</p> <p>18 A But -- but hang on a moment.</p> <p>19 Q Okay.</p> <p>20 A Clearly I haven't had time to dissect</p> <p>21 all this stuff (indicating).</p> <p>22 Q Sure.</p> <p>23 A And I don't know how many pages there</p> <p>24 are, but it's quite a little lot, it looks. So</p>	<p>95</p> <p>1 A Yes.</p> <p>2 Q Do you know any of those individuals?</p> <p>3 A The answer is I don't think so. I</p> <p>4 deal with thousands of people a year, you know.</p> <p>5 I mean --</p> <p>6 Q I'm just looking for your -- your best</p> <p>7 recollections.</p> <p>8 A Yes.</p> <p>9 Q Okay, do you see almost in the middle</p> <p>10 of the page, it says, "Weekly Meeting"?</p> <p>11 A Yes.</p> <p>12 Q All right, and then underneath there,</p> <p>13 there's a list of bullet points?</p> <p>14 A Yes.</p> <p>15 Q I'd like to direct you to one of the</p> <p>16 bullet points toward the middle of the bottom, it</p> <p>17 says, "Trial design/Issues"?</p> <p>18 A Yes, yes.</p> <p>19 Q Then the third bullet underneath that</p> <p>20 says, "Worse case: we have to attack the trial</p> <p>21 design if we do not see the results we want."</p> <p>22 Do you see that?</p> <p>23 A Yes.</p> <p>24 Q Have you heard that phrase before</p>
<p>94</p> <p>1 I'm not quite sure what you mean, but anyhow --</p> <p>2 Q Okay, what I propose is that I'll</p> <p>3 ask -- start asking you questions about this, and</p> <p>4 to the extent you think maybe you'd like to look</p> <p>5 at the rest of it, then you can go back and look</p> <p>6 at it.</p> <p>7 A Yes.</p> <p>8 Q Does that seem fair?</p> <p>9 A (Gesturing).</p> <p>10 Q Okay. Well, starting the</p> <p>11 second-to-last page, do you see the top of the</p> <p>12 page, it says, "Updated: CLASS Steering</p> <p>13 Committee"?</p> <p>14 A Yeah.</p> <p>15 Q Okay, then under "Required Attendees",</p> <p>16 do you see there's several individuals listed</p> <p>17 there?</p> <p>18 A Yes.</p> <p>19 Q Do you know any of those individuals</p> <p>20 personally?</p> <p>21 A I don't think so.</p> <p>22 Q All right, do you see a few lines</p> <p>23 underneath that, there's a list of those</p> <p>24 attending?</p>	<p>96</p> <p>1 "attack a trial design"?</p> <p>2 A That specific phrase, no.</p> <p>3 Q In the context of a clinical trial, do</p> <p>4 you have an understanding of what that means?</p> <p>5 A We have to criticize it. We have to</p> <p>6 say it's meaningless, it never will produce an</p> <p>7 answer, I assume, but that's an assumption. What</p> <p>8 else can it mean?</p> <p>9 Q All right, I'd like you to take a look</p> <p>10 at the Letter to the Editor again --</p> <p>11 A Yes.</p> <p>12 Q -- Exhibit 31. The second page, the</p> <p>13 Bates number ending 958, Bates ending 958, the</p> <p>14 same page we were looking at before --</p> <p>15 A All right.</p> <p>16 MR. NELSON: I don't know if this has Bates</p> <p>17 numbers on this version.</p> <p>18 MR. MONTGOMERY: Oh, I'm sorry. The second</p> <p>19 page.</p> <p>20 THE WITNESS: Can you just give me a second,</p> <p>21 please?</p> <p>22 BY MR. MONTGOMERY:</p> <p>23 Q Sure. I'm going to ask you about the</p> <p>24 same quote that we went through before.</p>



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<p>97</p> <p>1 A (Witness reviewing document). So now 2 we're going back to the letters? 3 Q Right. 4 A Yes. 5 Q All right, the second page of 6 Exhibit 31 -- 7 A You had me. I was slightly faked out 8 because they were talking VIGOR, and I'm 9 obviously going to be looking at different things 10 from you. 11 Q Right. Okay, so on the second page of 12 Exhibit 31 -- 13 A Yes. 14 Q Do you remember the language I read 15 into the record earlier that we agreed to call 16 informative censoring? 17 A Yes. 18 Q Okay, I'm not going to read it again, 19 but take a look at it again. 20 My question to you is whether or not 21 that theory constitutes attacking the trial 22 design? 23 MR. HALPER: Objection, calls for 24 speculation.</p>	<p>99</p> <p>1 let's disregard Exhibit 27 then, the class 2 steering document that we looked at, but -- we 3 did talk about just the phrase "attacking the 4 trial design" and what you generally understand 5 that to mean. 6 A Yeah. 7 Q So I'm not asking with -- you know, 8 anything with regard to the other document. 9 A Yes. 10 Q But just looking at the Letter to the 11 Editor and the informative censoring theory in 12 that letter -- 13 A Yeah. 14 Q -- would you understand that to be 15 attacking the trial design? 16 MR. HALPER: Objection to form. 17 THE WITNESS: Well, I said it's critiquing. 18 And, here, the people -- the phrase that you used 19 or the bits that you used are from the people who 20 did the trial, Silverstein and others, but it's 21 basically anything -- any criticism of the 22 design, you could call an attack on the design 23 and could say, Well, that's a criticism we're 24 trying to deal with and so on.</p>
<p>98</p> <p>1 THE WITNESS: I need help here. 2 BY MR. MONTGOMERY: 3 Q Sure. 4 A This is talking about the class 5 steering group attacking the steering -- the 6 design of the VIGOR study; is that correct? 7 Q I can't tell you that. You have to 8 interpret the document to the best of your 9 ability -- 10 A So I do. 11 Q -- how you understand it. 12 A However, it comes under the Trial 13 design/Issues, "Do not want Merck to start with a 14 story." And the reason I'm asking this is that 15 it seems to be a different design that's being 16 attacked by a different group. 17 Q Right. 18 A And so that you're -- the exact way 19 that you've phrased the question sounded a little 20 odd to me. 21 Q Okay, I think I can simplify it for 22 you. 23 A Thank you. 24 Q For the purposes of this question,</p>	<p>100</p> <p>1 MR. MONTGOMERY: I would like to ask the -- 2 THE WITNESS: That -- 3 MR. MONTGOMERY: I'm sorry, go ahead. 4 THE WITNESS: Okay. It gives the wrong 5 impression of what I feel about this. 6 BY MR. MONTGOMERY: 7 Q How is that? 8 A Well, if you don't report it at all, 9 how can anyone attack what seems not to have been 10 done, least of all the authors. 11 Q And I do want you to make sure 12 whenever I'm asking you a question that you think 13 that -- 14 A Yeah. 15 Q -- your answer fully reflects -- 16 A Yeah. 17 Q -- your view. So, all right, I'd like 18 to ask the court reporter to mark what will be 19 Exhibit 50. No, what is already Exhibit 37. 20 MR. NELSON: Excuse me, is this document 21 you just gave us 37 or is it 50? 22 MR. MONTGOMERY: It's 37. 23 MR. NELSON: Okay. 24</p>

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<p>101</p> <p>1 BY MR. MONTGOMERY:</p> <p>2 Q As always, you can read as much of it</p> <p>3 as you want. I'm going to only ask you about the</p> <p>4 second full paragraph in the first page.</p> <p>5 For the record, Exhibit 37 is an</p> <p>6 e-mail from Mona Wahba to Leland Loose and Ethan</p> <p>7 Weiner dated February 16th, 2000.</p> <p>8 A (Reviewing document).</p> <p>9 Q All right, on the first page of</p> <p>10 Exhibit 37, the second full paragraph that starts</p> <p>11 "Not for awhile yet," the second-to-last sentence</p> <p>12 reads, "Believe it or not a draft manuscript has</p> <p>13 already been written with a sort of a fill in the</p> <p>14 blanks depending upon what actually happens."</p> <p>15 Do you see that?</p> <p>16 A Yes.</p> <p>17 Q Are you familiar with the practice of</p> <p>18 drafting a manuscript before the results have</p> <p>19 been received?</p> <p>20 A It doesn't work like that. Yes and</p> <p>21 no. It doesn't work like that. I am very</p> <p>22 familiar with the idea that when you -- when you</p> <p>23 write a grant request, a very convenient thing to</p> <p>24 do is to rough out tables and rough out possible</p>	<p>103</p> <p>1 THE WITNESS: Obviously, you can -- (witness</p> <p>2 reviewing document).</p> <p>3 MR. MONTGOMERY: For the record, Exhibit 38</p> <p>4 is an e-mail from Nancy Tam, T-A-M, to Kenneth</p> <p>5 Verburg dated April 4th, 2000 with an attachment.</p> <p>6 BU MR. MONTGOMERY:</p> <p>7 Q All right, does the attachment to the</p> <p>8 e-mail in Exhibit 38 appear to be sort of a draft</p> <p>9 manuscript of the class study?</p> <p>10 A Yeah.</p> <p>11 Q And is it of the fill in the blanks</p> <p>12 variety described in Exhibit 37?</p> <p>13 MR. HALPER: Objection to form.</p> <p>14 THE WITNESS: Yes, along those lines.</p> <p>15 BY MR. MONTGOMERY:</p> <p>16 Q All right, would you look at what's</p> <p>17 the thirteenth page of the manuscript, Bates</p> <p>18 number ending 910? Do you see the section</p> <p>19 entitled "Results" on that page?</p> <p>20 A Yes.</p> <p>21 Q And do you see all the Xs with</p> <p>22 percentages after them?</p> <p>23 A Yes.</p> <p>24 Q And is the -- is that sort of draft</p>
<p>102</p> <p>1 results because you have by -- you have to do</p> <p>2 what are called power calculations, that is, how</p> <p>3 much difference might you expect that Celebrex</p> <p>4 might be compared with Naprosyn, and if that's</p> <p>5 the case, how many patients will you need because</p> <p>6 this can mean hundreds of millions of dollars to</p> <p>7 your company and to the patients, much more</p> <p>8 importantly.</p> <p>9 So you have to do a lot of stuff right</p> <p>10 there beforehand, and writing a paper in rough</p> <p>11 draft right at the start is a smart thing to do.</p> <p>12 I don't think it's talking about that, but still</p> <p>13 he might be. It's a smart thing to do because it</p> <p>14 tells you -- it reminds you of all those things</p> <p>15 you've got to have and have got to be able to</p> <p>16 justify later.</p> <p>17 Writing the full thing is a little</p> <p>18 odd, and, of course -- but if it was done by Fred</p> <p>19 Silverstein and gang, I'd say fair enough, you</p> <p>20 had a special look. I don't know who had the</p> <p>21 first look here.</p> <p>22 MR. MONTGOMERY: I'd like to ask the court</p> <p>23 reporter to -- well show the witness what's</p> <p>24 previously been marked as Exhibit 38.</p>	<p>104</p> <p>1 manuscript usual in your experience?</p> <p>2 A In my ex -- I don't know because I --</p> <p>3 I would say this is way more than what I was</p> <p>4 talking about.</p> <p>5 Q And you don't know whether that's</p> <p>6 unusual or not?</p> <p>7 A I don't know.</p> <p>8 Q Okay, would you please turn to the</p> <p>9 third page of Exhibit 38? Did you want to expand</p> <p>10 on your --</p> <p>11 A I don't know because we see the</p> <p>12 finished result. We never see this.</p> <p>13 Q So it's the -- please turn to the</p> <p>14 third page of Exhibit 38. It's the second page</p> <p>15 of the manuscript.</p> <p>16 A (Witness so doing).</p> <p>17 Q All right, do you see the section</p> <p>18 entitled "Methods" on that page?</p> <p>19 A (Nodding).</p> <p>20 Q All right, I'm going to read the first</p> <p>21 sentence into the record. It says, "Patients</p> <p>22 with OA or RA were enrolled into one of two</p> <p>23 studies simultaneously conducted for a period of</p> <p>24 up to 65 weeks." Do you see that?</p>

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<p>105</p> <p>1 A Yes.</p> <p>2 Q And had that language been included in</p> <p>3 the JAMA article, would you have understood that</p> <p>4 the class study lasted longer than six months?</p> <p>5 MR. HALPER: Objection, no foundation.</p> <p>6 THE WITNESS: Yeah. Well, yes.</p> <p>7 BY MR. MONTGOMERY:</p> <p>8 Q Would you --</p> <p>9 A I was -- forgive me, I was confused by</p> <p>10 the objection.</p> <p>11 Q Sure. You can -- you can just answer</p> <p>12 my question. You don't have to --</p> <p>13 MR. NELSON: Dr. Rennie, unless I tell you</p> <p>14 that you shouldn't answer, then you should answer</p> <p>15 over the objection, you know. But always give</p> <p>16 the guy time to object, time to think about your</p> <p>17 answer, but then if you with formulate an answer,</p> <p>18 do so.</p> <p>19 THE WITNESS: My problem wasn't that. My</p> <p>20 problem was whether 65 weeks was longer than six</p> <p>21 months, and I thought that that was self-evident,</p> <p>22 but I could see there was something else going on</p> <p>23 that I didn't appreciate. And I wasn't being</p> <p>24 rude. I was -- that's what stopped me suddenly.</p>	<p>107</p> <p>1 Q Had that language been included in the</p> <p>2 JAMA article, would you have understood the class</p> <p>3 study to have lasted longer than six months?</p> <p>4 A Yes.</p> <p>5 Q I'd like to ask the witness to look at</p> <p>6 what's previously been marked as Exhibit 21.</p> <p>7 A (Witness so doing).</p> <p>8 Q Have you ever seen Exhibit 21 before?</p> <p>9 A No.</p> <p>10 Q Have you seen final reports of other</p> <p>11 clinical studies before?</p> <p>12 A Yes.</p> <p>13 Q Does this look like it's the final</p> <p>14 report of the class study?</p> <p>15 A I suppose.</p> <p>16 Q All right, can you tell me the</p> <p>17 document date as it's reported on the first page?</p> <p>18 A The 25th of May 2000.</p> <p>19 Q And is that prior to when the JAMA</p> <p>20 article was published?</p> <p>21 A Right. It's a month after the</p> <p>22 lockdown date, I think, of all the data, so --</p> <p>23 Q But it is before the publication of</p> <p>24 the JAMA article; is that correct?</p>
<p>106</p> <p>1 BY MR. MONTGOMERY:</p> <p>2 Q Sure. Let me just ask again. He can</p> <p>3 object again, and then you can answer again to</p> <p>4 the extent you can.</p> <p>5 A Yes.</p> <p>6 Q Had the JAMA article as it was</p> <p>7 published included the language that I just read</p> <p>8 into the record, would you have understood that</p> <p>9 the class study lasted longer than six months?</p> <p>10 MR. HALPER: Objection, foundation.</p> <p>11 THE WITNESS: Yes.</p> <p>12 BY MR. MONTGOMERY:</p> <p>13 Q Would you turn to the eighth page of</p> <p>14 the manuscript, Bates number ending 905?</p> <p>15 A (Witness so doing).</p> <p>16 Q All right, do you see the section</p> <p>17 entitled "Outcome Measures" on that page?</p> <p>18 A Yes.</p> <p>19 Q All right, the first sentence of that</p> <p>20 reads, "The primary end point with the incidence</p> <p>21 of upper GI ulcer complications during the period</p> <p>22 of drug administration up to 65 weeks". Do you</p> <p>23 see that?</p> <p>24 A Yeah.</p>	<p>108</p> <p>1 A Right.</p> <p>2 Q All right, would you take a look at</p> <p>3 the third page, please, Bates number ending 925?</p> <p>4 A Yes.</p> <p>5 Q All right, do you see on that page</p> <p>6 there's a section entitled "Methodology" on the</p> <p>7 second half of the page?</p> <p>8 A Yes.</p> <p>9 Q All right, I think it's approximately</p> <p>10 the third sentence, it begins, "Treatment</p> <p>11 duration". Do you see that?</p> <p>12 A Yes.</p> <p>13 Q I'm going to read it into the record.</p> <p>14 It says, "Treatment duration lasted for at least</p> <p>15 26 weeks, with a maximum potential treatment of</p> <p>16 52 or 65 weeks."</p> <p>17 A Yes. Yes.</p> <p>18 Q If that language had been included in</p> <p>19 the JAMA article, would you have understood that</p> <p>20 the class study lasted longer than six months?</p> <p>21 MR. HALPER: Objection --</p> <p>22 THE WITNESS: Yes.</p> <p>23 MR. HALPER: (Continuing) -- foundation.</p> <p>24 THE WITNESS: Yes.</p>

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<p>109</p> <p>1 BY MR. MONTGOMERY:</p> <p>2 Q Yeah. All right, do you see</p> <p>3 underneath that there's a section entitled</p> <p>4 "Number of Patients"?</p> <p>5 A Yes.</p> <p>6 Q All right, the second sentence of that</p> <p>7 reads, "A total of 8,059 patients were enrolled,</p> <p>8 of whom 5 -- 4,573 completed six months of</p> <p>9 treatment and 3,409 completed the study." Do</p> <p>10 you see that?</p> <p>11 A Yes.</p> <p>12 Q Had that language been included in the</p> <p>13 JAMA article, would you have understood that the</p> <p>14 class study lasted longer than six months?</p> <p>15 MR. HALPER: Objection, foundation.</p> <p>16 THE WITNESS: Yes.</p> <p>17 BY MR. MONTGOMERY:</p> <p>18 Q All right, now I'd like you to go back</p> <p>19 to the JAMA article, which is Exhibit 3.</p> <p>20 A (Witness so doing).</p> <p>21 Q All right, I believe you testified</p> <p>22 before that you read this article when it was</p> <p>23 originally published; is that correct?</p> <p>24 A Yes. I haven't read it for six years.</p>	<p>111</p> <p>1 longer, so it became irrelevant. Do you see what</p> <p>2 I'm saying?</p> <p>3 Q Sure. Let me rephrase the question</p> <p>4 then. As you're sitting here today --</p> <p>5 A Yes.</p> <p>6 Q -- reading the language that I just</p> <p>7 read to you --</p> <p>8 A Yes.</p> <p>9 Q -- does that specific language</p> <p>10 communicate that the class study lasted longer</p> <p>11 than six months?</p> <p>12 A Not necessarily.</p> <p>13 Q Okay. Could you turn to the second</p> <p>14 page, please?</p> <p>15 A (Witness so doing).</p> <p>16 Q Do you see there's a heading "Study</p> <p>17 Protocol" in the middle of that page?</p> <p>18 A Yes.</p> <p>19 Q All right, I'd like you to look at the</p> <p>20 first paragraph there underneath "Study Protocol"</p> <p>21 at the last sentence. I'm going to read that</p> <p>22 into the record.</p> <p>23 A Yeah.</p> <p>24 Q It says, "After a baseline visit,</p>
<p>110</p> <p>1 Q Okay. I'd like you to look at --</p> <p>2 A So nearly six years.</p> <p>3 Q -- on the first -- I'd like you to</p> <p>4 look at the first page under the section entitled</p> <p>5 "Participants". Do you see that?</p> <p>6 A Yes.</p> <p>7 Q The second sentence reads, "A total of</p> <p>8 4573 patients (57%) received treatment for 6</p> <p>9 months." Do you --</p> <p>10 A Yes.</p> <p>11 Q -- see that?</p> <p>12 A Yes.</p> <p>13 Q When you read that originally, did you</p> <p>14 understand that the class study lasted longer</p> <p>15 than six months?</p> <p>16 A I didn't reach an opinion on that.</p> <p>17 Q Okay. Based upon everything that you</p> <p>18 read in the JAMA article, do you know whether or</p> <p>19 not you believed that the class study lasted</p> <p>20 longer than six months?</p> <p>21 A I don't know, and I'll tell you why.</p> <p>22 Because I was told there was something wrong with</p> <p>23 this, that's the very first reason that I read</p> <p>24 it. In other words, I was told it had lasted</p>	<p>112</p> <p>1 follow-up clinics -- clinic visits took place at</p> <p>2 weeks 4, 13, and 26 after the initial dose of</p> <p>3 medication, and every 13 weeks thereafter."</p> <p>4 A Hum.</p> <p>5 Q "All patients were provided an</p> <p>6 opportunity to complete a minimum of 6 months of</p> <p>7 treatment." Do you see that?</p> <p>8 A Yeah, I saw it.</p> <p>9 Q Do you recall how you interpreted that</p> <p>10 sentence the first time you read the document?</p> <p>11 A No.</p> <p>12 Q All right, sitting here today, does</p> <p>13 that communicate to you that the class study</p> <p>14 lasted longer than six months?</p> <p>15 A Hang on. (Reviewing document).</p> <p>16 I'm trying to determine when the first doses were</p> <p>17 given, see, because certainly it looks as though</p> <p>18 it was longer than that there, but -- every 13</p> <p>19 weeks thereafter, it doesn't add up to 26, but I</p> <p>20 don't know -- from this, I certainly can't</p> <p>21 remember what I thought. What I can see here is</p> <p>22 that it lasted six months.</p> <p>23 Q All right, do you recall in the final</p> <p>24 report that we just talked about the duration was</p>

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<p>113</p> <p>1 talked about as a maximum period of 52 or 65</p> <p>2 weeks?</p> <p>3 A Yes.</p> <p>4 Q Is -- is that disclosed in the --</p> <p>5 A I don't see it.</p> <p>6 Q -- in the quote that I just read to</p> <p>7 you from the --</p> <p>8 A No, I don't see it.</p> <p>9 Q You have to let me finish my question.</p> <p>10 I'm sorry, let me --</p> <p>11 A I apologize.</p> <p>12 Q That's okay. Starting again, the</p> <p>13 final report, Exhibit 21, that we looked at --</p> <p>14 A Yeah.</p> <p>15 Q -- indicated that there was a maximum</p> <p>16 potential treatment period of 52 or 65 weeks; is</p> <p>17 that right?</p> <p>18 A Yes.</p> <p>19 Q All right. Now, the excerpt from the</p> <p>20 JAMA article that I just read to you, did that</p> <p>21 disclose that fact?</p> <p>22 A Yes.</p> <p>23 MR. HALPER: The document speaks for</p> <p>24 itself.</p>	<p>115</p> <p>1 there anything in the language that you just read</p> <p>2 from the JAMA article that indicates that the</p> <p>3 trial lasted between 52 and 65 weeks?</p> <p>4 A No.</p> <p>5 Q I'd like to show the witness what's</p> <p>6 previously been marked as Exhibit 32. You can</p> <p>7 always read the whole thing. I'm only going to</p> <p>8 ask you about the second page.</p> <p>9 A Yes.</p> <p>10 Q If you start in the middle of the</p> <p>11 first column that says "Secondly" and read</p> <p>12 through the bottom of that column.</p> <p>13 A (Reviewing document). Okay.</p> <p>14 Q All right, have you ever seen</p> <p>15 Exhibit 32 before?</p> <p>16 A Yes.</p> <p>17 Q And is it an article from the British</p> <p>18 Medical Journal dated June 1st, 2002?</p> <p>19 A Yes.</p> <p>20 Q Did you read it at the time of its</p> <p>21 publication?</p> <p>22 A It's hard to know. I know Peter Juni</p> <p>23 fairly well, had a drink with him.</p> <p>24 Q And have you read it since that you</p>
<p>114</p> <p>1 BY MR. MONTGOMERY:</p> <p>2 Q All right, could you turn to the third</p> <p>3 page of Exhibit 3, Bates number ending 880?</p> <p>4 A Yeah.</p> <p>5 Q Do you see the "Statistical Analysis"</p> <p>6 section?</p> <p>7 A Yes.</p> <p>8 Q All right, I -- the second paragraph</p> <p>9 there that starts "Homogeneity" --</p> <p>10 A Yes.</p> <p>11 Q -- would you read starting from there</p> <p>12 to the end of the page, please?</p> <p>13 A Yes.</p> <p>14 Q I'm not going to read it into the</p> <p>15 record because it's too long.</p> <p>16 A Okay, "Homogeneity of the treatment</p> <p>17 group --</p> <p>18 Q No, no, you don't have to read it out</p> <p>19 loud, just to yourself.</p> <p>20 MR. NELSON: No, don't read it.</p> <p>21 BY MR. MONTGOMERY:</p> <p>22 Q But let me know when you're done.</p> <p>23 A (Reviewing document). Yes.</p> <p>24 Q All right, sitting here today, is</p>	<p>116</p> <p>1 can recall?</p> <p>2 A I don't imagine so. It's in my</p> <p>3 head --</p> <p>4 Q Okay.</p> <p>5 A -- mostly.</p> <p>6 Q All right, would you turn to the</p> <p>7 second page of Exhibit 32?</p> <p>8 A Yes.</p> <p>9 Q The last full paragraph on that -- on</p> <p>10 the first column that starts "Publishing", do you</p> <p>11 see that?</p> <p>12 A Yes.</p> <p>13 Q And I'm going to read the first</p> <p>14 sentence into the record. It says, "Publishing</p> <p>15 and distributing overoptimistic short term data</p> <p>16 using post hoc changes to the protocol, while</p> <p>17 omitting disappointing long term data of two</p> <p>18 trials, which involved large numbers of</p> <p>19 volunteers, is misleading." Do you see that?</p> <p>20 A Yes.</p> <p>21 Q Would you disagree with that</p> <p>22 statement?</p> <p>23 A Precisely.</p> <p>24 Q And do you believe that that's what</p>

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<p>117</p> <p>1 the authors of the JAMA article did in this case?</p> <p>2 A Yes.</p> <p>3 Q All right, above -- the paragraph</p> <p>4 right above that --</p> <p>5 A Yes.</p> <p>6 Q -- it says -- that paragraph begins</p> <p>7 with the sentence, "Secondly, the flawed findings</p> <p>8 published in the original article appear to be</p> <p>9 widely distributed and believed." Do you see</p> <p>10 that?</p> <p>11 A Yes.</p> <p>12 Q And by "original article", do you take</p> <p>13 that to mean the JAMA article?</p> <p>14 A Yes.</p> <p>15 Q And do you agree with that statement?</p> <p>16 A Yes.</p> <p>17 Q All right. All right, going back to</p> <p>18 the last full paragraph in that column, in the</p> <p>19 middle of it, there's a sentence that begins</p> <p>20 "Consequently". Do you see that?</p> <p>21 A Yes.</p> <p>22 Q I'm going to read that into the</p> <p>23 record. It says, "Consequently, CLASS may still</p> <p>24 be relied on by many physicians without reference</p>	<p>119</p> <p>1 can't remember what the policy was, but it's</p> <p>2 almost certain that I did.</p> <p>3 Q Why don't you take a minute and read</p> <p>4 through the first page at least and see if it</p> <p>5 refreshes your recollection?</p> <p>6 A Yeah. Oh, wait a minute, I'm not</p> <p>7 allowed to -- (gesturing).</p> <p>8 Q You can mark up his copy.</p> <p>9 MR. NELSON: Yeah, that's true. Go ahead.</p> <p>10 THE WITNESS: Thank you. (Reviewing</p> <p>11 document). Yeah, well, I've got the sense of</p> <p>12 what's new, sort of.</p> <p>13 BY MR. MONTGOMERY:</p> <p>14 Q Did you participate in the change of</p> <p>15 policy that's articulated in Exhibit 40?</p> <p>16 A Yes.</p> <p>17 Q And what role did you have in that</p> <p>18 change of policy?</p> <p>19 A Well, it's -- it's been a -- I've</p> <p>20 drawn attention and helped discuss -- I've drawn</p> <p>21 attention to lots of problems that people have</p> <p>22 had at my own and other journals, and so we've</p> <p>23 been -- you know, it's been an internal</p> <p>24 discussion. And because I've been working on</p>
<p>118</p> <p>1 to these flaws." Do you see that?</p> <p>2 A Yes.</p> <p>3 Q And do you take "these flaws" to mean</p> <p>4 the flaws enumerated above in the article?</p> <p>5 A Yes.</p> <p>6 Q And do you agree with that assessment?</p> <p>7 A Yes.</p> <p>8 Q All right, I'd like to show the</p> <p>9 witness what's previously been marked as</p> <p>10 Exhibit 40. Have you seen Exhibit 40 before?</p> <p>11 A Yes.</p> <p>12 Q Is it an editorial from JAMA dated</p> <p>13 July 12th, 2006?</p> <p>14 A Yes.</p> <p>15 Q Did you read this editorial when it</p> <p>16 was published?</p> <p>17 A I suppose so. I've read it.</p> <p>18 Q Okay, and does it concern a change in</p> <p>19 JAMA's conflict of interest policy?</p> <p>20 A Yes.</p> <p>21 Q And did you have any role in the</p> <p>22 change in that policy that this editorial</p> <p>23 discusses?</p> <p>24 A Now you're going to embarrass me. I</p>	<p>120</p> <p>1 this longer than most, a lot longer than most,</p> <p>2 despite myself, people listen or --</p> <p>3 Q Can you explain what the change in</p> <p>4 policy was basically?</p> <p>5 A "JAMA will begin requiring all authors</p> <p>6 to disclose all potential conflicts of interest</p> <p>7 in the Acknowledgement section."</p> <p>8 The point is to put them all there so</p> <p>9 that the editors can decide for the readers what</p> <p>10 are relevant, and since the editors should</p> <p>11 largely butt out, it's a matter of putting it all</p> <p>12 out there.</p> <p>13 This isn't to say that they are wrong,</p> <p>14 just so that people know, and a lot of it's about</p> <p>15 the date and so on, and it has to be done at the</p> <p>16 time of submission.</p> <p>17 Q All right. Now, I'd like to just</p> <p>18 shift gears for a quick second and ask you --</p> <p>19 earlier, I believe you testified that you</p> <p>20 belonged to an organization with Dr. Wright or</p> <p>21 that Dr. Wright also belongs to?</p> <p>22 A Apparently.</p> <p>23 Q Do you recall the name of that</p> <p>24 organization?</p>

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<p style="text-align: right;">121</p> <p>1 A Yes, the Cochrane Collaboration, 2 C-O-C-H-R-A-N-E. 3 Q And what's the purpose of that group? 4 A The purpose is to examine the 5 evidence, scientifically the evidence for what 6 are called interventions, everything from surgery 7 to every form of treatment for whatever. And 8 this has required recruiting somewhere between 9 twelve and twenty thousand experts in this from 10 all over the world and getting them to work for 11 nothing, and it's been very successful. 12 Q Have you worked directly with 13 Dr. Wright on any projects with that group? 14 A No. 15 Q Do you know Dr. Wright personally? 16 A No. 17 Q Have you ever worked with him 18 professionally? 19 A No. And I'm sure that after the 20 letter that I sent him, which I know was biting, 21 we never shall. 22 MR. MONTGOMERY: All right, I have no 23 further -- 24 THE WITNESS: I know that I never got a</p>	<p style="text-align: right;">123</p> <p>1 Q You had no responsibility at all for 2 the publication of the article; isn't that right? 3 A Correct. 4 Q You'd never heard of the class study 5 prior to publication of the article? 6 A Correct. 7 Q You didn't discuss the class study or 8 the article with any of your colleagues at JAMA 9 prior to publication -- 10 A No. 11 Q -- isn't that true? 12 A No, absolutely. 13 Q After the publication of the article 14 in JAMA, what, if anything, did you do to 15 familiarize yourself with the study or the 16 article? 17 A As I remember, and as I think I've 18 said, I read the article. I certainly read -- I 19 certainly spoke with my colleagues, particularly 20 Dr. DeAngelis, who told me what had happened. 21 By the way, this is after the -- it 22 was about this time that those letters came, the 23 Wright letter to me which came because of 24 Cochrane, the Hrachovec letter, I have no idea</p>
<p style="text-align: right;">122</p> <p>1 reply. That's all I can remember about it. 2 MR. MONTGOMERY: All right, I have no 3 further questions at this time. We are going to 4 take a quick break, defense counsel is going to 5 prepare some questions, and then I might have 6 some follow-up, but, otherwise, I'm done. 7 THE WITNESS: Okay, fine. Thank you. 8 MR. MONTGOMERY: Let's go off the record. 9 THE WITNESS: Thank you. 10 THE VIDEOGRAPHER: This is the end of 11 Video 3. The time is 4:45 p.m., and the running 12 time of this tape is 54 minutes and 20 seconds. 13 (Recess taken.) 14 THE VIDEOGRAPHER: This is the start of 15 Tape 4. The time is 4:52 p.m. 16 MR. HALPER: Good evening, Dr. Rennie. We 17 met earlier, but my name is Jason Halper, and I 18 represent the Defendants in this case. 19 CROSS EXAMINATION 20 BY MR. HALPER: 21 Q It's true, isn't it, that you did not 22 participate in any way in JAMA's publication of 23 the class article? 24 A Yes, it's true, I did not.</p>	<p style="text-align: right;">124</p> <p>1 why it came to me, both of which went on. And at 2 that point -- 3 Q I'm sorry, is "that point" about mid 4 2001? 5 A It was sometime before the publication 6 of the letters, obviously, and the exact date 7 could be pinned down by when the data appeared on 8 the website of the FDA and then people started 9 writing in, Wright and Hrachovec and no -- I 10 don't know if there were others. 11 Q So your involvement in connection with 12 the class study started after the Advisory 13 Committee hearings in February 2001 when the data 14 was posted on the web -- the FDA website? 15 A That's right. And my involvement at 16 that point was put it in a Letter to the Editor 17 or, if it's in a Letter to the Editor, send it to 18 the person dealing with Letters, whom I believe 19 I've seen from one of those was Lurie, Steve 20 Lurie at the time. I don't know if that was 21 right or not, but I think that makes sense. 22 But I -- you know, we have a guy who 23 does Letters. 24 Q That wasn't your responsibility?</p>

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<p style="text-align: right;">125</p> <p>1 A That was not my responsibility. It</p> <p>2 used -- one of the many things I did way back,</p> <p>3 not then.</p> <p>4 Q So the letters that were published in</p> <p>5 JAMA regarding the class article from</p> <p>6 Silverstein, from Wright, you had nothing to do</p> <p>7 with; is that right?</p> <p>8 A Nothing to do with those.</p> <p>9 Q Okay, you didn't review them</p> <p>10 beforehand?</p> <p>11 A No.</p> <p>12 Q You didn't approve them?</p> <p>13 A No.</p> <p>14 Q You didn't discuss them with your</p> <p>15 colleagues at JAMA?</p> <p>16 A No.</p> <p>17 Q Okay.</p> <p>18 A Dis -- I cannot say whether I</p> <p>19 discussed them or not, I just don't know. You</p> <p>20 see, since they came to me and I forwarded them</p> <p>21 and I know that I wrote Wright this lengthy email</p> <p>22 explaining how things worked, I can't say that I</p> <p>23 didn't discuss these letters, but I had no</p> <p>24 decision power over them whatsoever.</p>	<p style="text-align: right;">127</p> <p>1 the publication of the letters, these slides</p> <p>2 (indicating) were made in I imagine 2002 or so</p> <p>3 because they were made by my ex-assistant, who</p> <p>4 came on in 2001.</p> <p>5 Q And the slides you're referring to,</p> <p>6 that's what's been marked as Exhibit 42?</p> <p>7 A Yes.</p> <p>8 Q You didn't prepare these slides?</p> <p>9 A "Carol," I said, and then I said,</p> <p>10 "make one like that (indicating) and with a</p> <p>11 jagged end at the bottom to indicate just what</p> <p>12 it's called."</p> <p>13 The next one I definitely made myself.</p> <p>14 The next one, she made. I said again, "Make it."</p> <p>15 And in the slide, the middle bit is yellowed. In</p> <p>16 other words, "In retrospect, we acknowledged that</p> <p>17 we could have avoided," which is the letter from</p> <p>18 Silverstein, which it was -- my bias was it was</p> <p>19 not as frank an admission of -- well, it wasn't</p> <p>20 right, I suppose.</p> <p>21 Q The first and third pages of</p> <p>22 Exhibit 42 are copies of pages from the class</p> <p>23 article and the Silverstein reply, correct?</p> <p>24 A Correct.</p>
<p style="text-align: right;">126</p> <p>1 Q Do you recall having any discussion</p> <p>2 with your colleagues at JAMA regarding the</p> <p>3 substance of any of those letters?</p> <p>4 A No, I don't recall that.</p> <p>5 Q So to the extent you're surmising that</p> <p>6 you might have discussed the letters, is it fair</p> <p>7 to say that it would have been the fact that you</p> <p>8 received a letter as opposed to the content of</p> <p>9 the letter?</p> <p>10 A Well, I certainly discussed the fact</p> <p>11 that I'd received them, and what I can't recall</p> <p>12 is how much more.</p> <p>13 Now, I undoubtedly -- it would be</p> <p>14 pretty weird not to have gone and discussed a bit</p> <p>15 more. I can't believe that I didn't, but it's</p> <p>16 that sort of memory that I have, I can't believe</p> <p>17 I didn't, but I can't tell you whether I did and</p> <p>18 with whom and so on.</p> <p>19 Q Fair enough. Okay, so sometime after</p> <p>20 February of 2001, you read the class article, you</p> <p>21 have discussions with some of your colleagues.</p> <p>22 Did you do anything else in connection with</p> <p>23 class?</p> <p>24 A I don't think so except sometime after</p>	<p style="text-align: right;">128</p> <p>1 Q What you said you prepared is the</p> <p>2 second page of Exhibit 42, correct?</p> <p>3 A Yes.</p> <p>4 Q What sources, if any, did you consult</p> <p>5 to make Exhibit 42, the second page of</p> <p>6 Exhibit 42?</p> <p>7 A It's hard to know exactly, but as I</p> <p>8 said to Mr. Montgomery, I'm sure that I looked at</p> <p>9 the FDA website. I can't believe I didn't is how</p> <p>10 I'm putting that. I have no evidence one way --</p> <p>11 I'm sure I read the paper enough to see how the</p> <p>12 two things squared. I may have read the comments</p> <p>13 of others, I don't know.</p> <p>14 Q Everything you're testifying to, I</p> <p>15 take it you don't have a specific recollection of</p> <p>16 actually doing any of those things to prepare the</p> <p>17 second page of Exhibit 42?</p> <p>18 A No.</p> <p>19 Q What you were testifying to is what</p> <p>20 you imagined your -- what your practice is</p> <p>21 typically?</p> <p>22 A Yes.</p> <p>23 Q Okay, but you don't recall what, if</p> <p>24 anything, you consulted in preparing the second</p>



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<p>129</p> <p>1 page of Exhibit 42; is that correct?</p> <p>2 A No. This was part of a lecture which</p> <p>3 gradually developed on authorship. So that, no</p> <p>4 doubt, when the -- when the VIGOR study came</p> <p>5 through, I added that. That was later.</p> <p>6 Q But just so -- I'm sorry, just so I'm</p> <p>7 clear, you don't recall what you consulted to</p> <p>8 make Exhibit 42, correct?</p> <p>9 A No. Except I do know "editors</p> <p>10 exasperated and furious" were definitely</p> <p>11 Dr. DeAngelis. And "laughing to the bank", I</p> <p>12 have no evidence for that beyond that's what it</p> <p>13 looked like to me. Still does.</p> <p>14 Q Do you have a recollection at any time</p> <p>15 of looking at the FDA website regarding class?</p> <p>16 A No.</p> <p>17 Q Do you -- how much time did you spend</p> <p>18 looking at the FDA website regarding class?</p> <p>19 A Well -- I don't know.</p> <p>20 Q Sitting here today, do you have any</p> <p>21 recollection of what the underlying data is</p> <p>22 regarding the class study?</p> <p>23 A No.</p> <p>24 Q Do you know the difference in the</p>	<p>131</p> <p>1 a recollection?</p> <p>2 A -- and that I got information from</p> <p>3 other people too.</p> <p>4 Q Okay.</p> <p>5 A My guess might be -- no, I don't --</p> <p>6 all of this is guess. Of course, I don't.</p> <p>7 Otherwise, I'd have said differently.</p> <p>8 Q Understood. Just so we're clear, you</p> <p>9 don't have a recollection of looking at data on</p> <p>10 the FDA website regarding class, correct?</p> <p>11 A I have a recollection of looking at</p> <p>12 the FDA data on class, but I cannot tell you</p> <p>13 whether there were P values, if they're</p> <p>14 important. Confidence intervals might be a great</p> <p>15 deal more interesting to me. I cannot tell you</p> <p>16 now exactly what was there.</p> <p>17 I just -- my bias, as I've said, is</p> <p>18 I'm unlikely to have made this (indicating) if</p> <p>19 none of it was true at the time in thea that I</p> <p>20 could try and confirm, that's all.</p> <p>21 Q Again, though, you don't have sitting</p> <p>22 here today a recollection of going on the FDA</p> <p>23 website regarding class, do you?</p> <p>24 A Well, I have a recollection that I did</p>
<p>130</p> <p>1 results at six months versus the entire study</p> <p>2 period?</p> <p>3 A Not now, but I am sure that I did.</p> <p>4 The wooley results, that's why I made the slide</p> <p>5 or --</p> <p>6 Q What I'm talking about is did -- do</p> <p>7 you know the different P values at six months</p> <p>8 versus the entire study values?</p> <p>9 A No.</p> <p>10 Q Do you think you ever knew that?</p> <p>11 A I don't know.</p> <p>12 Q You don't remember what data you</p> <p>13 looked at, correct?</p> <p>14 A No.</p> <p>15 Q And do you know that you ever looked</p> <p>16 at any data on the FDA website?</p> <p>17 A Well, I've said as I think I did.</p> <p>18 Q But you don't have a specific</p> <p>19 recollection of it?</p> <p>20 A What was -- this was five years ago.</p> <p>21 So I guess I can't remember exactly what it was.</p> <p>22 What I do remember was that I wasn't the only</p> <p>23 person looking --</p> <p>24 Q But talking about you, you don't have</p>	<p>132</p> <p>1 it.</p> <p>2 Q Other than having a recollection that</p> <p>3 you did it, do you have any other recollection</p> <p>4 about, for instance --</p> <p>5 A No, because, as I've said, I've done</p> <p>6 it frequently with all sorts of drugs. And</p> <p>7 that's the problem, you see. You know, I --</p> <p>8 (gesturing).</p> <p>9 Q Okay, so other than recalling that you</p> <p>10 went on the website, you don't recall anything</p> <p>11 else about what was on the website, correct?</p> <p>12 A None, not a thing.</p> <p>13 Q Okay. Or how long you spent?</p> <p>14 A No.</p> <p>15 Q Okay. You wouldn't hold yourself out</p> <p>16 as an expert on the data underlying the class</p> <p>17 study, would you?</p> <p>18 A No.</p> <p>19 Q Okay, would you hold yourself out as</p> <p>20 an expert on the class study?</p> <p>21 A No.</p> <p>22 Q How about an expert on arthritis?</p> <p>23 A No.</p> <p>24 Q An expert on rheumatology?</p>

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<p style="text-align: right;">133</p> <p>1 A No.</p> <p>2 Q Are you an expert on statistics?</p> <p>3 A No.</p> <p>4 Q On COX-2s?</p> <p>5 A No.</p> <p>6 Q On NSAIDs?</p> <p>7 A No.</p> <p>8 Q So coming back --</p> <p>9 A I've produced a book on how to analyze</p> <p>10 trials and medical studies.</p> <p>11 Q What's the title of that book?</p> <p>12 A The Users Guides to the Medical</p> <p>13 Literature.</p> <p>14 Q Okay, when was that published?</p> <p>15 A 2002, I suppose, and we just finished</p> <p>16 an update. It's a fat book and it's a thin book,</p> <p>17 and it's soon going to be an electronic book</p> <p>18 because it sold quite well. I didn't get a penny</p> <p>19 for --</p> <p>20 MR. NELSON: Let the record show that the</p> <p>21 witness -- the witness -- let the record show the</p> <p>22 witness was looking at me, and I was looking away</p> <p>23 from him.</p> <p>24 THE WITNESS: In other words, what I'm</p>	<p style="text-align: right;">135</p> <p>1 BY MR. HALPER:</p> <p>2 Q Okay, just so we're clear, sometime --</p> <p>3 A I have not done this sort (indicating)</p> <p>4 of trial. I'm at the other end of the -- I'm at</p> <p>5 the editing end and publishing end. I'm not at</p> <p>6 the doing an end of trials like this.</p> <p>7 Q Other than the one time that you</p> <p>8 testified to?</p> <p>9 A I think to compare the two would be</p> <p>10 like comparing a bicycle with a Ferrari, and this</p> <p>11 (indicating) we would hope to be a Ferrari.</p> <p>12 Q By "this" you mean class?</p> <p>13 A That type of trial.</p> <p>14 Q Is it fair to say that you've never</p> <p>15 authored a published study similar to class?</p> <p>16 A Correct.</p> <p>17 Q Sometime after February 2001, your,</p> <p>18 for lack of a better word, involvement or</p> <p>19 investigation of class started, correct? Is that</p> <p>20 correct?</p> <p>21 A I looked at it, I read it.</p> <p>22 Q And that involvement consisted of</p> <p>23 reading the general publication, right --</p> <p>24 A (Nodding).</p>
<p style="text-align: right;">134</p> <p>1 trying to say is trials tend to be similar,</p> <p>2 observational studies tend to be similar, and</p> <p>3 editors of general medical journals tend to be</p> <p>4 trained in that sort of thing.</p> <p>5 BY MR. HALPER:</p> <p>6 Q How many clinical trials, published</p> <p>7 clinical trials have you authored?</p> <p>8 A One, I believe. I think that's what I</p> <p>9 said.</p> <p>10 Q When was that?</p> <p>11 A 1976.</p> <p>12 Q What topics?</p> <p>13 A It's become a classic. Hum?</p> <p>14 Q In what topic? What was the subject</p> <p>15 of the study?</p> <p>16 A It's called -- it's in my CV. It's</p> <p>17 called the -- well, the subject was acute</p> <p>18 mountain sickness. I did the trial in the</p> <p>19 Himalayas, and that's not as easy as you might</p> <p>20 think.</p> <p>21 Q I don't think it's easy.</p> <p>22 MR. NELSON: And it's not even as easy as</p> <p>23 that.</p> <p>24</p>	<p style="text-align: right;">136</p> <p>1 Q You need to give a verbal response.</p> <p>2 A Yes.</p> <p>3 Q Okay.</p> <p>4 A Apologies. Sorry, Debbie.</p> <p>5 Q Thank you. (Continuing) -- speaking</p> <p>6 with your colleagues at JAMA, correct --</p> <p>7 A Yes.</p> <p>8 Q -- and your recollection of going on</p> <p>9 the FDA website once, correct?</p> <p>10 A And then getting these letters --</p> <p>11 Q And getting the letters.</p> <p>12 A -- which were quite striking.</p> <p>13 Q Did you do anything else in connection</p> <p>14 with class?</p> <p>15 A I made three slides.</p> <p>16 Q Exhibit 42?</p> <p>17 A Yes.</p> <p>18 Q Okay, did you do anything else in</p> <p>19 connection with class?</p> <p>20 A Nothing else I could do.</p> <p>21 Q Okay. Speaking with your</p> <p>22 colleagues --</p> <p>23 THE VIDEOGRAPHER: I'm sorry, I was just</p> <p>24 trying to get Mr. Nelson's attention. I had to</p>

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<p style="text-align: right;">137</p> <p>1 turn your mic off because handling the mic is</p> <p>2 something that makes noise on the record. So</p> <p>3 you're off until you put it on.</p> <p>4 BY MR. HALPER:</p> <p>5 Q Focusing on what you testified to, you</p> <p>6 spoke with colleagues, how many colleagues did</p> <p>7 you speak with regarding class?</p> <p>8 A I don't know.</p> <p>9 Q Did you speak with anyone besides</p> <p>10 Dr. DeAngelis?</p> <p>11 A I'm sure I did, but I don't know who.</p> <p>12 Q Okay.</p> <p>13 A My guess -- yeah, certainly I did,</p> <p>14 certainly. For all I know, we had a discussion</p> <p>15 about it. I talk with colleagues about stuff</p> <p>16 every day.</p> <p>17 Q Do you have a recollection of talking</p> <p>18 about class with anyone other than Dr. DeAngelis?</p> <p>19 A Any editor.</p> <p>20 Q I'm sorry, any colleague at JAMA.</p> <p>21 A Yeah. I am certain that I have</p> <p>22 discussed it with Dr. Phil Fontanarosa. The</p> <p>23 others, I can't say.</p> <p>24 Q How many times did you discuss class</p>	<p style="text-align: right;">139</p> <p>1 how many conversations did you have with her</p> <p>2 regarding class?</p> <p>3 A I can't say now.</p> <p>4 Q How long did any conversation with her</p> <p>5 last?</p> <p>6 A I don't know.</p> <p>7 Q Where did any of these conversations</p> <p>8 occur?</p> <p>9 A I imagine -- most, you see, would tend</p> <p>10 to be on the phone.</p> <p>11 Q Just I don't want you to imagine. If</p> <p>12 you don't recall, that's fine.</p> <p>13 What I'm asking you is do you have a</p> <p>14 recollection of where you were when you spoke to</p> <p>15 Dr. DeAngelis regarding class?</p> <p>16 A No. But since I'm here for a short</p> <p>17 amount of time, my imagination wasn't based on</p> <p>18 just nothing. I'm just saying likelihoods would</p> <p>19 tell me that.</p> <p>20 Q I take it from your answer, you don't</p> <p>21 have a specific recollection --</p> <p>22 A Correct.</p> <p>23 Q -- of the conversation?</p> <p>24 A No.</p>
<p style="text-align: right;">138</p> <p>1 with Dr. Fontanarosa?</p> <p>2 A I don't know.</p> <p>3 Q How long did any of those discussions</p> <p>4 last?</p> <p>5 A I don't know.</p> <p>6 Q What was discussed at any of those</p> <p>7 conversations?</p> <p>8 A The reporting of class, what actually</p> <p>9 happened.</p> <p>10 Q Where did these conversations take</p> <p>11 place?</p> <p>12 A Sometimes on the phone, sometimes</p> <p>13 face-to-face. I'm usually here once a month or</p> <p>14 something.</p> <p>15 Q But you don't recall whether it was</p> <p>16 one conversation or more?</p> <p>17 A No.</p> <p>18 Q And you don't recall how long the</p> <p>19 conversation lasted?</p> <p>20 A No.</p> <p>21 Q You don't recall, I assume, what he</p> <p>22 said to you or what you said to him?</p> <p>23 A No.</p> <p>24 Q The conversation with Dr. DeAngelis,</p>	<p style="text-align: right;">140</p> <p>1 Q And you don't recall then what she</p> <p>2 said to you and what you said to her?</p> <p>3 A I recall that she was -- I do recall</p> <p>4 very, very strongly that she was -- on more than</p> <p>5 one occasion, she'd said she was exasperated and</p> <p>6 furious.</p> <p>7 Q Did she say anything else?</p> <p>8 A She didn't even say that. She just</p> <p>9 gave the -- I think Dr. DeAngelis, whom is just a</p> <p>10 wonderful person, you'll know when she's</p> <p>11 exasperated and furious.</p> <p>12 Q I know.</p> <p>13 A Okay.</p> <p>14 Q Do you recall her conveying any</p> <p>15 substantive information regarding class to you?</p> <p>16 A Yes.</p> <p>17 Q What did she convey?</p> <p>18 A Well, she said, "This is the problem,</p> <p>19 they didn't tell us that data." I said, "I know</p> <p>20 because I've had these two letters," the first</p> <p>21 time we talked. She said, "One's from British</p> <p>22 Columbia, one's from Washington. Are they</p> <p>23 connected?" I said, "Oh, come on, Cathy, there's</p> <p>24 no connection between those places, they're just</p>

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<p style="text-align: right;">141</p> <p>1 Northwest. How could they be?" And then I</p> <p>2 explained why one of them had come to me and the</p> <p>3 other one was a mystery. I think she must have</p> <p>4 been sitting in the audience, this Hrachovec</p> <p>5 person.</p> <p>6 I know that those -- that sequence</p> <p>7 happened in a conversation with Cathy. Other</p> <p>8 than that, I don't know.</p> <p>9 Q She didn't tell you anything about the</p> <p>10 data underlying class, did she?</p> <p>11 A No.</p> <p>12 Q Did Dr. Fontanarosa ever tell you</p> <p>13 anything about the data underlying class?</p> <p>14 A Well, you've said "or somebody else".</p> <p>15 You know, I like data. I mean it's -- and</p> <p>16 somebody must have done that.</p> <p>17 Q But my question was did</p> <p>18 Dr. Fontanarosa tell you?</p> <p>19 A I thought you said "or anyone else".</p> <p>20 Q I may have -- I just missed on his</p> <p>21 name, but I was trying to say Dr. Fontanarosa.</p> <p>22 Did he tell you anything?</p> <p>23 A I don't know.</p> <p>24 Q And you don't have a recollection of</p>	<p style="text-align: right;">143</p> <p>1 BMJ one.</p> <p>2 Q The one that JAMA --</p> <p>3 A In other words, the paper that formed</p> <p>4 Exhibit whatever, and this would be at a meeting,</p> <p>5 you know.</p> <p>6 Q The meeting --</p> <p>7 A It's the British Medical Journal paper</p> <p>8 that he wrote with this -- the Dutch woman. I</p> <p>9 forget her name.</p> <p>10 Q You would have had a discussion with</p> <p>11 Dr. Juni regarding the BMJ editorial after the</p> <p>12 editorial was published, correct?</p> <p>13 A Yes.</p> <p>14 A It's No. 32. Oh, yes, yes.</p> <p>15 Q You don't have a recollection of</p> <p>16 speaking to Dr. Juni before he published the BMJ</p> <p>17 editorial, do you?</p> <p>18 A Oh, sure, yeah.</p> <p>19 Q Regarding class?</p> <p>20 A Not about class, no.</p> <p>21 Q Is it fair to say, Dr. Rennie, that</p> <p>22 other than reading the article and going to the</p> <p>23 FDA website, there were no other sources for your</p> <p>24 knowledge of substantive information regarding</p>
<p style="text-align: right;">142</p> <p>1 speaking with anyone other than Dr. DeAngelis or</p> <p>2 Dr. Fontanarosa regarding class, do you?</p> <p>3 A Specifically, no.</p> <p>4 Q And you don't have a recollection of</p> <p>5 how long conversations with either Dr. DeAngelis</p> <p>6 or Dr. Fontanarosa, how long those conversations</p> <p>7 lasted?</p> <p>8 A No.</p> <p>9 Q Or how many there were?</p> <p>10 A No. I say specifically no because I</p> <p>11 may have surely spoken with Peter Juni about this</p> <p>12 and with his colleague Matt Egger, who's also of</p> <p>13 Burn &amp; Bristol, and I must surely have</p> <p>14 spoken -- you know, but I can't give you the date</p> <p>15 or the time --</p> <p>16 Q Or what was discussed?</p> <p>17 A -- more than that. Just the class</p> <p>18 study, that's all.</p> <p>19 Q But you don't recall what specifically</p> <p>20 about the class study was discussed with any of</p> <p>21 these individuals, correct?</p> <p>22 A What I discussed with Dr. Juni as I</p> <p>23 recollect were two papers of his, one, an older</p> <p>24 one, which we published in JAMA, the other this</p>	<p style="text-align: right;">144</p> <p>1 class?</p> <p>2 A No, it's not fair. What I'm saying is</p> <p>3 I don't know. I'm also saying it is highly</p> <p>4 likely, probable that I did have other sources,</p> <p>5 but I don't know what they were at this length of</p> <p>6 time.</p> <p>7 Q And those sources would be your</p> <p>8 conversations with people?</p> <p>9 A Or what they've written.</p> <p>10 Q Sitting here today, do you recall</p> <p>11 reading any other articles regarding class other</p> <p>12 than Letters to Editors?</p> <p>13 A Well, there've been a number that have</p> <p>14 been written, as you know. All right, here's</p> <p>15 one. I have -- I've discussed the class study</p> <p>16 with David Henry of the University of New South</p> <p>17 Wales, who published a -- an obser -- a very big</p> <p>18 analysis of multiple observational trials of</p> <p>19 COX-2 inhibitors, coxibs like this, and that</p> <p>20 specific class came up. I --</p> <p>21 Q When did that conversation occur?</p> <p>22 A Last year. I've discussed the matter</p> <p>23 with David Graham, who's a physician and an M --</p> <p>24 a public health person at the FDA.</p>

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<p>145</p> <p>1 Q Well, let me try and narrow it a</p> <p>2 little. Between the publication of the --</p> <p>3 between February of 2001 and June 2002 -- and</p> <p>4 I'll tell you June 2002 is when the Juni</p> <p>5 editorial was published.</p> <p>6 A Yeah.</p> <p>7 Q (Continuing) -- who did you discuss</p> <p>8 class with?</p> <p>9 A I don't know, but I have certainly</p> <p>10 discussed it with a number of people since.</p> <p>11 Q Since June 2002?</p> <p>12 A One remembers most -- most recently.</p> <p>13 Q Do you understand that the Plaintiffs</p> <p>14 in this litigation are claiming that the JAMA</p> <p>15 publication of class caused Pharmacia's common</p> <p>16 stock to trade higher, at a higher price than it</p> <p>17 otherwise would have?</p> <p>18 A (Nodding).</p> <p>19 Q Do you understand that the Plaintiffs</p> <p>20 are claiming that?</p> <p>21 MR. MONTGOMERY: Object to form. Go ahead.</p> <p>22 BY MR. HALPER:</p> <p>23 Q Do you understand Plaintiffs are</p> <p>24 claiming that?</p>	<p>147</p> <p>1 would wreck me and wreck my journal.</p> <p>2 Q But I take it the answer is you don't</p> <p>3 know?</p> <p>4 A No, I do not know.</p> <p>5 Q And you also don't know whether or not</p> <p>6 Pharmacia's stock was trading at an inflated</p> <p>7 price due to the JAMA article, correct?</p> <p>8 A Haven't a clue.</p> <p>9 Q And you don't know whether the</p> <p>10 reprints of the JAMA article that were</p> <p>11 distributed had any impact on the Pharmacia stock</p> <p>12 price, do you?</p> <p>13 MR. MONTGOMERY: Object to form.</p> <p>14 THE WITNESS: No. I didn't even know there</p> <p>15 were any until it came up, I think. So I don't</p> <p>16 even know if that's true.</p> <p>17 BY MR. HALPER:</p> <p>18 Q And you don't know whether the JAMA</p> <p>19 reprints that were distributed caused anyone to</p> <p>20 buy or sell Pharmacia stock, do you?</p> <p>21 A I can't.</p> <p>22 MR. MONTGOMERY: Object to form.</p> <p>23 THE WITNESS: No.</p> <p>24 MR. HALPER: Thank you.</p>
<p>146</p> <p>1 A Actually, I thought it was what</p> <p>2 Mr. Montgomery told me, that -- wasn't that part</p> <p>3 of your opening remarks? I thought so.</p> <p>4 I understood that -- I've just found</p> <p>5 out that that is what this is all about.</p> <p>6 Q Okay, you're not an expert on the</p> <p>7 stock market, are you?</p> <p>8 A Oh, boy, no.</p> <p>9 Q You're not an investment professional,</p> <p>10 correct?</p> <p>11 A You got it. That's, no, I'm not.</p> <p>12 Q I take it you have no basis -- let me</p> <p>13 withdraw that.</p> <p>14 You don't know whether or not the</p> <p>15 price of Pharmacia stock was impacted by the JAMA</p> <p>16 article, do you?</p> <p>17 A No, I don't.</p> <p>18 Q You don't know whether any investors</p> <p>19 bought or sold Pharmacia stock based on the JAMA</p> <p>20 article, do you?</p> <p>21 A It's a great deal more than not</p> <p>22 knowing. I don't want to know.</p> <p>23 Q Okay.</p> <p>24 A I can't be involved in that. That</p>	<p>148</p> <p>1 BY MR. HALPER:</p> <p>2 Q If you could take a look at</p> <p>3 Exhibit 22, which is the email from Mona Wahba to</p> <p>4 Stephen Cristo?</p> <p>5 A Got it.</p> <p>6 Q You got it? Do you recall</p> <p>7 Mr. Montgomery directing your attention to Mona</p> <p>8 Wahba's statement, "We are also cherry picking</p> <p>9 the data"?</p> <p>10 A Yes.</p> <p>11 Q Do you know Mona Wahba?</p> <p>12 A No.</p> <p>13 Q Do you know whether she worked for</p> <p>14 Pfizer or Pharmacia?</p> <p>15 A Well -- well, no, of course not, no.</p> <p>16 Q And I take it you also don't know --</p> <p>17 A Well, I mean I can see what her --</p> <p>18 what this says, what she's --</p> <p>19 Q Her address?</p> <p>20 A That's all.</p> <p>21 Q Okay.</p> <p>22 A And I went by that, actually. I --</p> <p>23 Q But because you don't know her, you</p> <p>24 don't know anything about her other than what you</p>

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<p>149</p> <p>1 see from reading the email, correct?</p> <p>2 A Right, grodan.pfizer.com.</p> <p>3 Q And when you say "pfizer.com", you're</p> <p>4 reading the Exhibit 22?</p> <p>5 A Yes.</p> <p>6 Q But you don't know Ms. Wahba, correct?</p> <p>7 A No, I do not.</p> <p>8 Q Okay, you don't know whether she had</p> <p>9 any involvement at all in the class study,</p> <p>10 correct?</p> <p>11 A I don't know anything about her at all</p> <p>12 apart from what I've been shown in the email.</p> <p>13 Q Okay. And you don't know, do you,</p> <p>14 whether or not in fact anyone cherry picked data</p> <p>15 based on Ms. Wahba's email?</p> <p>16 A That's putting it backwards, but no is</p> <p>17 the answer. I thought Miss -- Miss Wahba was</p> <p>18 saying that others cherry picked.</p> <p>19 Q Okay, do you know if Miss Wahba had</p> <p>20 any basis to make that statement?</p> <p>21 A "Using 6 months as a study duration"</p> <p>22 is what she puts, and so she provides her own</p> <p>23 basis for it right there. That's her definition,</p> <p>24 I believe, of cherry picking. And so I'd say,</p>	<p>151</p> <p>1 A Yes.</p> <p>2 Q But we can agree that you don't know</p> <p>3 Ms. Wahba, right?</p> <p>4 A Correct.</p> <p>5 Q We did agree that you don't know what,</p> <p>6 if any, involvement she had in class, correct?</p> <p>7 A Yes.</p> <p>8 Q So other than reading what's here, you</p> <p>9 have no basis to know whether or not Ms. Wahba</p> <p>10 was qualified to make the statement that's here,</p> <p>11 correct?</p> <p>12 A That's -- she's a physician. That's</p> <p>13 all I know about her, but I -- but my -- no.</p> <p>14 Q You have no basis to know whether</p> <p>15 she's qualified to make that statement, right?</p> <p>16 A No, apart from being a physician.</p> <p>17 Q Okay. If you turn to Exhibit 27,</p> <p>18 which is sort of the -- one of the somewhat</p> <p>19 thicker exhibits where you were directed to the</p> <p>20 second-to-last page, which is an email from</p> <p>21 Carolyn Wilson -- if you want to show him where</p> <p>22 it is?</p> <p>23 MR. NELSON: Oh, okay, yeah.</p> <p>24 THE WITNESS: No, I'll find it in a second.</p>
<p>150</p> <p>1 yes, I do know.</p> <p>2 Q You're reading the email, correct?</p> <p>3 A That's all I have.</p> <p>4 Q Okay, you don't know Ms. Wahba, right?</p> <p>5 A Not at all.</p> <p>6 Q You don't know what, if any,</p> <p>7 involvement she had in class, correct?</p> <p>8 A Of course not.</p> <p>9 Q You don't know what her basis is for</p> <p>10 making that statement, do you?</p> <p>11 A Yes, I do. "We are also cherry</p> <p>12 picking the data," which is the statement she</p> <p>13 makes. And she follows it in parentheses "using</p> <p>14 6 months as study duration." And that seems to</p> <p>15 me the basis -- or, perhaps, it's clear I'm --</p> <p>16 you and I are misunderstanding each other or I'm</p> <p>17 misunderstanding you.</p> <p>18 Q You're reading the email, correct?</p> <p>19 A I agree, she might --</p> <p>20 Q Based --</p> <p>21 A She might be a myth, after all.</p> <p>22 Q Based on the email, you're inferring</p> <p>23 that her rationale for the cherry picking</p> <p>24 statement is the use of six-month data, correct?</p>	<p>152</p> <p>1 Is it 38?</p> <p>2 MR. NELSON: It's 27.</p> <p>3 THE WITNESS: So -- exactly. So 25 --</p> <p>4 MR. MONTGOMERY: They're not in order,</p> <p>5 right.</p> <p>6 THE WITNESS: No. No, no, no, I quit.</p> <p>7 MR. NELSON: Okay, here it is.</p> <p>8 THE WITNESS: 27, thank you.</p> <p>9 MR. NELSON: Okay.</p> <p>10 BY MR. HALPER:</p> <p>11 Q Do you recall Mr. Montgomery showing</p> <p>12 you Exhibit 27?</p> <p>13 A Yes.</p> <p>14 Q And on the page with the Bates stamp</p> <p>15 ending 816, I believe you testified that you</p> <p>16 don't know any of the individuals listed as</p> <p>17 required attendees, correct?</p> <p>18 A I believe not. That's -- it is</p> <p>19 correct as far as I know.</p> <p>20 Q Okay, and you also don't know any of</p> <p>21 the people listed as attending, correct?</p> <p>22 A That's correct.</p> <p>23 Q Okay, and I -- just for clarity, I</p> <p>24 take it you don't know who Carolyn Wilson is?</p>

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<p>153</p> <p>1 A No. I now know I'm going to be made</p> <p>2 to look like a clown, but, no, I don't.</p> <p>3 Q You don't know, for instance, what her</p> <p>4 position is?</p> <p>5 A No.</p> <p>6 Q Do you recall that Mr. Montgomery</p> <p>7 directed you to a bullet point that says, "Worse</p> <p>8 case: We have to attack the trial design if we</p> <p>9 do not see the results we want"? Do you recall</p> <p>10 that statement?</p> <p>11 A Yes.</p> <p>12 Q In the email, correct?</p> <p>13 A Yes.</p> <p>14 Q Okay. You don't have any basis to</p> <p>15 know whether anyone acted on that statement, do</p> <p>16 you?</p> <p>17 A No.</p> <p>18 Q Exhibit 49 is the -- I'll butcher the</p> <p>19 name -- the Hrachovec.</p> <p>20 A 46.</p> <p>21 Q 49.</p> <p>22 A 49, sorry.</p> <p>23 Q The Hrachovec letter.</p> <p>24 MR. NELSON: This is it.</p>	<p>155</p> <p>1 isn't that right?</p> <p>2 A This was a Merck author who was taken</p> <p>3 off -- she was on the web version and then was --</p> <p>4 disappeared.</p> <p>5 Q You're --</p> <p>6 A And she was a Merck author, right.</p> <p>7 Q Right. It's not about the class</p> <p>8 study, is it?</p> <p>9 A No.</p> <p>10 Q Are you aware of --</p> <p>11 A I believe not. This was -- I think</p> <p>12 the first author was David Solomon, David --</p> <p>13 Avorn, and various people like that were on it,</p> <p>14 but she was just offed.</p> <p>15 Q This situation that you're quoted</p> <p>16 talking about --</p> <p>17 A Yes.</p> <p>18 Q -- in Exhibit 48, that doesn't involve</p> <p>19 class, does it?</p> <p>20 A Not at all.</p> <p>21 Q Are you aware of the situation you're</p> <p>22 describing or commenting on in Exhibit 48</p> <p>23 applying to class?</p> <p>24 A No.</p>
<p>154</p> <p>1 THE WITNESS: Oh, I'm sorry, yes. Yeah.</p> <p>2 BY MR. HALPER:</p> <p>3 Q Well, I don't need -- let's see if I</p> <p>4 can do it without showing it to you.</p> <p>5 You recall that you received a draft</p> <p>6 Letter to the Editor from Hrachovec --</p> <p>7 A I did.</p> <p>8 Q -- correct?</p> <p>9 A Yes.</p> <p>10 Q You had no role in the publication of</p> <p>11 that letter --</p> <p>12 A Right.</p> <p>13 Q -- correct?</p> <p>14 A None.</p> <p>15 Q If you could turn to Exhibit 48, which</p> <p>16 is the Wall Street Journal Asia article from May</p> <p>17 2004?</p> <p>18 A This is forty --</p> <p>19 Q 48.</p> <p>20 A Thank you.</p> <p>21 Q Okay, and do you recall testifying</p> <p>22 about your quote in this article?</p> <p>23 A Yes.</p> <p>24 Q Your quote was in reference to Vioxx;</p>	<p>156</p> <p>1 Q You talked --</p> <p>2 A Except -- except there's the strange</p> <p>3 business of who signed the letter, but that's</p> <p>4 often a matter of contention.</p> <p>5 Q Silverstein's letter?</p> <p>6 A Right, his response.</p> <p>7 Q Right.</p> <p>8 A His rebuttal, if you like.</p> <p>9 Q But you have no reason to believe that</p> <p>10 what you're commenting on in Exhibit 48 happened</p> <p>11 in connection with the JAMA article --</p> <p>12 A No.</p> <p>13 Q -- on class, right?</p> <p>14 A No, none.</p> <p>15 Q Okay, and do -- do you have a reason</p> <p>16 to believe it happened with the Silverstein</p> <p>17 reply?</p> <p>18 A Well, we've all seen what happened</p> <p>19 there. This was a -- an exceptional case, I'd</p> <p>20 say, with a carefully negotiated response, as I</p> <p>21 now find out, because it's not exactly common for</p> <p>22 authors to come up here and meet with the Editor</p> <p>23 and the Executive Editor and then for a letter to</p> <p>24 be generated.</p>

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<p style="text-align: right;">157</p> <p>1 So my answer to that is it was 2 exceptional, very exceptional, that letter, for 3 that sequence of events to happen, that's all. 4 Q You're not aware of Dr. Silverstein 5 walking away from that letter, are you? 6 A No. 7 Q Are you aware of any of the authors of 8 that letter walking away from the letter? 9 MR. MONTGOMERY: Objection to form. 10 THE WITNESS: Well, I haven't had time to 11 read all the documents that I was given by 12 Mr. Montgomery concerning that very issue. I 13 just -- you know, just didn't -- haven't had 14 time. So I don't know whether they walked away. 15 I do remember that in one of the -- in 16 one of those specific documents, it says, Here's 17 the letter, we have to send it out to the rest. 18 This was me reading fast as I could. And that -- 19 so that whether they walked away or not is 20 unclear, but I'm -- I seem to remember those 21 words in that little packet to do with the -- 22 with the letter itself or if it was a -- 23 BY MR. HALPER: 24 Q Let's take a look at Exhibit 31, which</p>	<p style="text-align: right;">159</p> <p>1 what I've just said. 2 Q Okay. Let me try -- 3 A Am I wrong here? 4 Q No, no. Let me try and clarify it. I 5 think I'm being more simplistic than you. 6 A Well, I was -- I'm desperately trying 7 to help here. 8 Q In Exhibit 48, which was the Wall 9 Street -- that's okay, you don't have to go 10 there. It's the Wall Street Journal article. 11 A I have it. 12 Q Okay? You're commenting on a 13 situation of the Merck person asking to be taken 14 off as an author, correct? 15 A A paper. 16 Q A paper. Correct? And you testified 17 that you're not aware that anything like that 18 happened in connection with the JAMA publication 19 of the class study; is that right? 20 A I don't know whether she asked to be 21 taken off. She was taken off. 22 Q Okay. 23 A And I am not aware of that exact thing 24 happening, but it's a puzzle for me, given that I</p>
<p style="text-align: right;">158</p> <p>1 is Dr. Silverstein's reply letter. 2 A No, that wasn't -- of course, of 3 course, I'll do, but that wasn't what I was 4 talking about. 5 Q Oh. Well, that's what I was talking 6 about. 7 A I was talking about -- you asked a 8 question about the preparation of that letter and 9 whether anyone walked -- whether any of the 10 authors walked away from it, and I was about to 11 say it -- and I said I was fed some letters -- 12 Q Um-hum. 13 A Some -- sorry, some documents. And in 14 those documents, somebody says, I believe, We'll 15 have to -- here's the letter that we've prepared, 16 we'll have to show it to the other authors or to 17 the authors. 18 Q Um-hum. 19 A If that happened and their names don't 20 appear here, I cannot possibly know whether they 21 walked away, weren't shown it or what. 22 Q Okay. 23 A But all I can say is that I can't give 24 you a straight answer to that question beyond</p>	<p style="text-align: right;">160</p> <p>1 was given a document that suggested it. 2 Q Well, I'm focusing now on the 3 September of 2000 publication of the class study, 4 okay? That's Exhibit 3, where the seventeen 5 authors are listed. Do you want to get that? 6 A No, that's all right, I've got it. 7 Q You understand that the seventeen 8 authors are listed -- 9 A Right. 10 Q -- correct? Are you -- do you have 11 any reason to believe that any of those 17 12 authors at any time have in any way attempted to 13 distance themselves or not stand behind the JAMA 14 publication? 15 MR. MONTGOMERY: Object to form. 16 THE WITNESS: Well, as a matter of fact, I 17 do. Until I can look at that, that document that 18 I was provided with, if my recollection is 19 correct -- and I could be wrong. 20 BY MR. HALPER: 21 Q I think you're referring to 22 Exhibit 39. 23 A I could be completely wrong, but I 24 feel I've got the right to look --</p>



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<p>161</p> <p>1 Q Sure.</p> <p>2 A -- and check.</p> <p>3 Q Exhibit 39, which I think is the Goran</p> <p>4 Ando email of August 13th, 2001.</p> <p>5 A It says, "My recommendation," and "it"</p> <p>6 is Goran Ando -- or, no, George Geis says, "Once</p> <p>7 we receive everyone's comments we need to decide</p> <p>8 the next steps. My recommendation is that the</p> <p>9 letter to JAMA come from all the CLASS authors.</p> <p>10 Once we redraft the letter we would send it to</p> <p>11 the authors and get their buy-in with the intent</p> <p>12 of making the 10 day timeline imposed by JAMA.</p> <p>13 Do you agree?"</p> <p>14 And then -- and that was the last</p> <p>15 thing here. So when I read that, I say they</p> <p>16 might have walked away or run away or not gone</p> <p>17 through with his recommendation or anything. In</p> <p>18 other words, I have here in my hand something</p> <p>19 that makes me very uneasy of saying yes to</p> <p>20 your -- to your question, that's all.</p> <p>21 Q Okay.</p> <p>22 A And I won't say yes to it.</p> <p>23 Q Okay.</p> <p>24 A All right, that's all.</p>	<p>163</p> <p>1 BY MR. HALPER:</p> <p>2 Q But my question was, you know,</p> <p>3 putting -- taking into account what you've said</p> <p>4 about this document, that was part of my</p> <p>5 question, do you have any basis to believe that</p> <p>6 any of those seventeen individuals have attempted</p> <p>7 to walk away from or disavow the JAMA</p> <p>8 publication?</p> <p>9 MR. MONTGOMERY: Object to form.</p> <p>10 THE WITNESS: No, I don't.</p> <p>11 BY MR. HALPER:</p> <p>12 Q Okay, and if you look at the</p> <p>13 Silverstein reply, Exhibit 31, there are three</p> <p>14 authors listed Silverstein, Simon and Faich,</p> <p>15 correct?</p> <p>16 A Yes.</p> <p>17 Q Do you have any reason to believe that</p> <p>18 they have disavowed Exhibit 31 in any way?</p> <p>19 A No.</p> <p>20 Q We -- you testified earlier about</p> <p>21 guest authorship. Do you recall that?</p> <p>22 A Yes.</p> <p>23 Q If guest authorship occurs, does that</p> <p>24 necessarily mean that the article is incorrect?</p>
<p>162</p> <p>1 Q Let me --</p> <p>2 A That's what I was remembering.</p> <p>3 Q Do you know whether Dr. Geis's</p> <p>4 suggestion that the letter come from all the</p> <p>5 authors was acted on?</p> <p>6 A No idea.</p> <p>7 Q For all you know, it could have been a</p> <p>8 decision that had come from the three individuals</p> <p>9 who in fact authored the letter; isn't that true?</p> <p>10 A Could well be.</p> <p>11 Q You don't know one way or the other,</p> <p>12 right?</p> <p>13 A No idea.</p> <p>14 Q Okay. My question is, and I am taking</p> <p>15 what you said, apart from Exhibit 39, okay, do</p> <p>16 you have any reason to believe that any of the</p> <p>17 seventeen authors of the JAMA article have</p> <p>18 attempted to distance themselves or disavow in</p> <p>19 any way the JAMA publication?</p> <p>20 MR. MONTGOMERY: Object to form.</p> <p>21 THE WITNESS: It's a bigger part. And the</p> <p>22 answer is no, I don't, but -- I'm waving this</p> <p>23 document -- I'd like to know more.</p> <p>24</p>	<p>164</p> <p>1 MR. MONTGOMERY: Object to form.</p> <p>2 THE WITNESS: Yes.</p> <p>3 BY MR. HALPER:</p> <p>4 Q If there's guest authorship, does it</p> <p>5 mean necessarily that -- other than who wrote it,</p> <p>6 does that -- does it mean that the article, the</p> <p>7 substance, is incorrect?</p> <p>8 A No.</p> <p>9 Q And if an article is ghost written,</p> <p>10 other than that fact, does the fact that it is</p> <p>11 ghost written mean necessarily that the article</p> <p>12 in substance is incorrect?</p> <p>13 MR. MONTGOMERY: Object to form.</p> <p>14 THE WITNESS: Yes. It's so fundamental.</p> <p>15 BY MR. HALPER:</p> <p>16 Q Do you have a reason to believe that</p> <p>17 the class publication was ghost written?</p> <p>18 MR. MONTGOMERY: Object to form.</p> <p>19 THE WITNESS: I have no idea who wrote it.</p> <p>20 BY MR. HALPER:</p> <p>21 Q Okay, and therefore, you don't know --</p> <p>22 you have no reason to believe it was ghost</p> <p>23 written?</p> <p>24 A I believe the authors must have</p>

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<p>165</p> <p>1 testified that they wrote it, and it definitely</p> <p>2 wasn't ghost written, therefore, but I --</p> <p>3 Q But just if something is ghost</p> <p>4 written, we assume some article was ghost</p> <p>5 written --</p> <p>6 A Yeah.</p> <p>7 Q -- I understand that what you said</p> <p>8 that it's fundamental.</p> <p>9 A Yeah, yeah, yeah.</p> <p>10 Q But does that mean that the substance</p> <p>11 of the article is necessarily incorrect?</p> <p>12 MR. MONTGOMERY: Object to form.</p> <p>13 THE WITNESS: Well, it depends upon what</p> <p>14 you mean by incorrect. It doesn't work like</p> <p>15 that, I'd say.</p> <p>16 BY MR. HALPER:</p> <p>17 Q Does it mean the data presented in a</p> <p>18 given article is incorrect?</p> <p>19 MR. MONTGOMERY: Object to form.</p> <p>20 THE WITNESS: Not necessarily. It doesn't</p> <p>21 mean necessarily it's incorrect, that's right,</p> <p>22 but it may mean that the whole setup or the</p> <p>23 particular data that are presented or the</p> <p>24 analysis or whatever are incorrect.</p>	<p>167</p> <p>1 paragraph in the second column starting, "This</p> <p>2 all implies", do you see that?</p> <p>3 A Yes.</p> <p>4 Q Okay. "This all implies that the data</p> <p>5 after 6 months are not valid for examining</p> <p>6 drug-induced GI toxicities. Based on these</p> <p>7 concerns, the authors concluded that the 6-month</p> <p>8 analyses of complicated ulcers and symptomatic</p> <p>9 ulcers were less subject to bias and would</p> <p>10 reflect true drug effects and therefore should be</p> <p>11 the basis of the report of the trial." Do you</p> <p>12 see that?</p> <p>13 A Yes.</p> <p>14 Q You don't have any basis to disagree</p> <p>15 with Dr. Silverstein's statement as to whether</p> <p>16 the post six month data is valid, do you?</p> <p>17 MR. MONTGOMERY: Object to form.</p> <p>18 THE WITNESS: Yes.</p> <p>19 BY MR. HALPER:</p> <p>20 Q You testified you didn't independently</p> <p>21 analyze the data, correct?</p> <p>22 A But you didn't ask me if it was</p> <p>23 independent, and it wasn't. I was told it was</p> <p>24 incorrect.</p>
<p>166</p> <p>1 BY MR. HALPER:</p> <p>2 Q But, again, you don't have any reason</p> <p>3 to believe that ghost writing occurred here,</p> <p>4 correct?</p> <p>5 A No.</p> <p>6 THE REPORTER: I'm sorry, what was your</p> <p>7 answer?</p> <p>8 THE WITNESS: No.</p> <p>9 BY MR. HALPER:</p> <p>10 Q If you'd turn to Exhibit 31, which is</p> <p>11 the Silverstein reply again?</p> <p>12 A Yes.</p> <p>13 Q You've testified already that you're</p> <p>14 not an expert in statistics, correct?</p> <p>15 A Correct.</p> <p>16 Q And you did not perform any</p> <p>17 independent statistical analysis of the class</p> <p>18 study data, did you?</p> <p>19 A No.</p> <p>20 Q Okay.</p> <p>21 A No, no.</p> <p>22 Q Let me read you a sentence or two from</p> <p>23 Dr. Silverstein's reply. If you look at his</p> <p>24 letter, Page 2 of Exhibit 31, the first full</p>	<p>168</p> <p>1 Q By who?</p> <p>2 A I believe Peter Juni, but I can't</p> <p>3 remember. I just -- I don't remember now.</p> <p>4 Q Okay, other than someone else telling</p> <p>5 you --</p> <p>6 A Right.</p> <p>7 Q -- that Dr. Silverstein is wrong --</p> <p>8 A Okay.</p> <p>9 Q -- do you have an opinion on whether</p> <p>10 or not Dr. Silverstein's statement that I just</p> <p>11 read to you is wrong?</p> <p>12 A No. My opinion was they didn't tell</p> <p>13 us.</p> <p>14 Q Understood. Putting that aside, you</p> <p>15 don't --</p> <p>16 A And, of course, I'm having difficulty</p> <p>17 putting that aside. It's huge. It's the</p> <p>18 elephant, really.</p> <p>19 Q For you. But you understand we're</p> <p>20 here on a securities litigation, correct?</p> <p>21 A (Nodding).</p> <p>22 Q Right?</p> <p>23 A I've got it.</p> <p>24 Q Okay. So what I'm asking you is, for</p>

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<p>169</p> <p>1 all you know, Dr. Silverstein's statement could</p> <p>2 very well be correct; isn't that true?</p> <p>3 MR. MONTGOMERY: Object to form.</p> <p>4 THE WITNESS: Well, if I'd been told it</p> <p>5 wasn't correct, how can I answer that in yes?</p> <p>6 I'd say no.</p> <p>7 BY MR. HALPER:</p> <p>8 Q You have no basis other than what</p> <p>9 Dr. Juni told you --</p> <p>10 A Or --</p> <p>11 Q -- to disagree with Dr. Silver --</p> <p>12 A Or whoever it was who told me.</p> <p>13 Q Sorry, I just need to finish the</p> <p>14 statement.</p> <p>15 A I'm --</p> <p>16 Q No. You have no basis other than what</p> <p>17 someone told you --</p> <p>18 A Yes.</p> <p>19 Q -- to disagree with --</p> <p>20 A Right.</p> <p>21 Q -- Dr. Silverstein's statement?</p> <p>22 A Right.</p> <p>23 MR. MONTGOMERY: Object to form.</p> <p>24</p>	<p>171</p> <p>1 results after six months are statistically</p> <p>2 suspect, if we assume that for a minute, isn't it</p> <p>3 true that the post six month dataset will not be</p> <p>4 instructive regarding the safety or efficacy of</p> <p>5 Celebrex?</p> <p>6 A That doesn't follow.</p> <p>7 MR. MONTGOMERY: Object to form.</p> <p>8 BY MR. HALPER:</p> <p>9 Q Why not?</p> <p>10 A The post six months -- what I have</p> <p>11 been told is that the post six months results,</p> <p>12 which are really the only important ones or the</p> <p>13 long ones are the most important ones, of course,</p> <p>14 with any drug like this, I'm told that they</p> <p>15 really overturned.</p> <p>16 BY MR. HALPER:</p> <p>17 Q But you --</p> <p>18 A Moreover, they didn't stick to the</p> <p>19 protocol, they changed it 'round. And that, of</p> <p>20 course, introduces a few statistical problems,</p> <p>21 again, I'm told, very severe statistical problems</p> <p>22 if you change the thing in -- especially, if you</p> <p>23 change it in analysis, during analysis.</p> <p>24 THE VIDEOGRAPHER: Pardon me, Counselor,</p>
<p>170</p> <p>1 BY MR. HALPER:</p> <p>2 Q And you have no independent basis to</p> <p>3 disagree with Dr. Silverstein's statement,</p> <p>4 correct?</p> <p>5 MR. MONTGOMERY: Object to form.</p> <p>6 THE WITNESS: Unless you can count the</p> <p>7 papers that have been written on it like Uni's</p> <p>8 and Graham's and so on. I don't know whether</p> <p>9 you'd call that independent. I would, you know.</p> <p>10 But did it come from my own analysis</p> <p>11 of the primary data? The answer is no.</p> <p>12 BY MR. HALPER:</p> <p>13 Q Okay, you didn't do anything to verify</p> <p>14 or refute Dr. Silverstein's statement, correct?</p> <p>15 A No.</p> <p>16 Q And therefore, based on your own work,</p> <p>17 you have no basis to refute Dr. Silverstein's</p> <p>18 statement, correct?</p> <p>19 A Right.</p> <p>20 MR. MONTGOMERY: Object to form.</p> <p>21 THE WITNESS: Because I'm not the expert of</p> <p>22 that.</p> <p>23 BY MR. HALPER:</p> <p>24 Q If Dr. Silverstein is correct and the</p>	<p>172</p> <p>1 I'm at the end of the tape.</p> <p>2 MR. HALPER: Okay.</p> <p>3 THE VIDEOGRAPHER: This the end of Tape 4.</p> <p>4 The time is 5:52 p.m. The running time of the</p> <p>5 tape is 1 hour and 32 seconds.</p> <p>6 (Recess taken.)</p> <p>7 THE VIDEOGRAPHER: This is the start of</p> <p>8 Tape 5. The time is 5:58 p.m.</p> <p>9 BY MR. HALPER:</p> <p>10 Q Dr. Rennie, if you'd turn to</p> <p>11 Exhibit 28 --</p> <p>12 A 28 is?</p> <p>13 Q -- which is the email from James</p> <p>14 Lefkowitz to Emilio Arbe.</p> <p>15 MR. NELSON: (Tendering document to</p> <p>16 witness).</p> <p>17 THE WITNESS: Thank you.</p> <p>18 MR. NELSON: You're welcome.</p> <p>19 BY MR. HALPER:</p> <p>20 Q And you were shown a statement on the</p> <p>21 third page of that email in Emilio Arbe's April</p> <p>22 9th, 2000 email, the third paragraph. Do you see</p> <p>23 that?</p> <p>24 A Yes.</p>

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<p>173</p> <p>1 Q Okay, that's the "with a bit of data 2 massage" paragraph, right? 3 A Yes. 4 Q Okay. Do you know Emilio Arbe? 5 A No. 6 Q Okay, do you know who he worked for at 7 this time? 8 A No. 9 Q Do you know what position he held at 10 this time? 11 A Somewhat junior to Jim Lefkowitz or 12 Magnus somebody. 13 Q But other than looking at the email, 14 you don't know what position he held? 15 A Oh, no, no. 16 Q And do you know what, if any, 17 involvement he had in the class study? 18 A Don't know. 19 Q And do you know whether or not he 20 actually had any basis for making the statements 21 that appear on Exhibit 28? 22 A Yes. 23 Q Why do you say that? 24 A Well, he writes here, "With a bit of</p>	<p>175</p> <p>1 BY MR. HALPER: 2 Q Okay. And do you have any reason to 3 believe that -- 4 A Well -- 5 Q -- Arbe is qualified to say whether or 6 not the reason that Geis and his team focused on 7 the six month data is simply to make the -- it'd 8 look better? 9 MR. NELSON: Do you have to change your 10 further -- your previous question -- or I mean 11 answer? Do you have to supplement it? 12 THE WITNESS: Yes. I was trying to say -- 13 you asked if he was qualified. I don't know his 14 degrees. 15 All I'm saying is that he wasn't 16 completely unqualified because I thought that the 17 points -- and I read this extremely rapidly and 18 only once -- that these were interesting 19 comments. 20 So he's not completely clueless, this 21 guy, and I'd say he was quite a critic. So 22 qualified, not qualified, I don't know, but I 23 certainly don't know whether he's got a degree. 24</p>
<p>174</p> <p>1 data massage, what Steve Geis and his team have 2 done is to focus on the 6 month data", and I 3 would say that that's incontrovertible, although 4 I'm sure that -- well, it's incontrovertible. 5 Q That Steve Geis and his team focused 6 on the six month data, correct? 7 A Well, the authors of this paper that 8 we published focused on the six month data. 9 Q Okay, that's true, right? 10 A Yes. 11 Q Okay. 12 A So you asked me is there a basis, and 13 I said yes. 14 Q But you don't know whether or not he 15 was involved in the class study, correct? 16 A No. 17 MR. MONTGOMERY: Object to form. 18 BY MR. HALPER: 19 Q So other than reading the email, you 20 don't know whether or not he was qualified to 21 make any of these statements -- 22 A No. 23 Q -- correct? 24 MR. MONTGOMERY: Object to form.</p>	<p>176</p> <p>1 BY MR. HALPER: 2 Q Well, you don't know Arbe, correct? 3 A No, not at all. 4 Q You don't know his degrees, right? 5 A No. 6 Q You don't know his position at this 7 time -- 8 A No. 9 Q -- correct? You don't know if he 10 knows Steve Geis, correct? 11 A Not at all. 12 Q If he doesn't know Steve Geis, is he 13 qualified to say why Steve Geis focused on the 14 six month data? 15 MR. MONTGOMERY: Object to form. 16 THE WITNESS: Well, he's pointing out what 17 they did. 18 BY MR. HALPER: 19 Q We can all agree that they focused on 20 the six month data, correct? 21 A Yes. 22 Q But he, Arbe, goes beyond that to say 23 why he thinks Geis focused on the six month data, 24 right?</p>

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<p>177</p> <p>1 A And my experience is that people focus</p> <p>2 on what they want to focus on, and optimists, as</p> <p>3 we all are, tend to do that. That's one of the</p> <p>4 big problems in reporting a medical research.</p> <p>5 And if Steve Geis did that, as he seems to have</p> <p>6 done, he's by no means a rarity.</p> <p>7 Q Okay, you don't know Steve Geis,</p> <p>8 correct?</p> <p>9 A Not at all.</p> <p>10 Q You don't know why he did anything he</p> <p>11 did in connection with class, right?</p> <p>12 A I'm just saying --</p> <p>13 Q Well --</p> <p>14 A No, I don't.</p> <p>15 Q Okay. And you don't know if Arbe</p> <p>16 knows Steve Geis, right?</p> <p>17 A No, I don't.</p> <p>18 Q And therefore, if he doesn't, he has</p> <p>19 no basis to so opine on why Steve Geis did</p> <p>20 anything he did in connection with class,</p> <p>21 correct?</p> <p>22 MR. MONTGOMERY: Object to form.</p> <p>23 THE WITNESS: Well, I can't draw that</p> <p>24 conclusion.</p>	<p>179</p> <p>1 isn't true. I do have a reason. This is how</p> <p>2 researchers behave.</p> <p>3 Q You're making a generalization, aren't</p> <p>4 you?</p> <p>5 A Indeed, yes, from evidence.</p> <p>6 Q But not regarding Steve Geis, correct?</p> <p>7 A No.</p> <p>8 Q And not regarding class, correct?</p> <p>9 A Correct.</p> <p>10 Q And not regarding Emilio Arbe,</p> <p>11 correct?</p> <p>12 A Correct.</p> <p>13 Q You don't know any of these people</p> <p>14 that we're talking about --</p> <p>15 A Correct.</p> <p>16 Q -- right?</p> <p>17 A I've said that.</p> <p>18 Q And so you don't know what -- Steve</p> <p>19 Geis, what he did in connection with class,</p> <p>20 correct?</p> <p>21 MR. MONTGOMERY: Object to form.</p> <p>22 BY MR. HALPER:</p> <p>23 Q I didn't say, Do you have any basis?</p> <p>24 I said, You don't know why he did what he did?</p>
<p>178</p> <p>1 BY MR. HALPER:</p> <p>2 Q Why?</p> <p>3 A For the reason I said. There's plenty</p> <p>4 of evidence for optimistic reporting. I'd say</p> <p>5 every week we have to change conclusions, and</p> <p>6 indeed, I know that this is correct because with</p> <p>7 two others -- I've just finished a study of 124</p> <p>8 metro analyses, and this will explain it. And</p> <p>9 the only differences one can see here are that</p> <p>10 those funded by sponsors with an interest in the</p> <p>11 answer have the same result as those that don't</p> <p>12 in the same area, hypertension, but those -- but</p> <p>13 the conclusions on the same data are optimistic.</p> <p>14 So when I say -- and that's just --</p> <p>15 that's my own study done with my own sweat of my</p> <p>16 own brow. When I say that this is how</p> <p>17 researchers are, I'd say I know how researchers</p> <p>18 are because I've studied it, and that's only one</p> <p>19 study of it.</p> <p>20 Now, our research was not on Steve</p> <p>21 Geis, who for all I -- I have no idea what he's</p> <p>22 like, but I'm just saying that this remark sounds</p> <p>23 like somebody making a remark that rings true.</p> <p>24 So when you say you have no reason, I'd say that</p>	<p>180</p> <p>1 A No.</p> <p>2 MR. MONTGOMERY: Object to form.</p> <p>3 BY MR. HALPER:</p> <p>4 Q And you don't know if Emilio Arbe has</p> <p>5 any reason that he knows --</p> <p>6 A No.</p> <p>7 Q -- why Steve Geis, what he -- did what</p> <p>8 he did --</p> <p>9 MR. MONTGOMERY: Object to form.</p> <p>10 BY MR. HALPER:</p> <p>11 Q (Continuing) -- in connection with</p> <p>12 class, do you?</p> <p>13 A Well, see, there we part company.</p> <p>14 Q Do you know --</p> <p>15 MR. NELSON: Excuse me, I think he's -- you</p> <p>16 know, if you ask a question, he's entitled to</p> <p>17 give an answer.</p> <p>18 MR. HALPER: Well, he said, "There we part</p> <p>19 company."</p> <p>20 MR. NELSON: Well, I don't know -- if</p> <p>21 that's a complete answer, then fine. Otherwise,</p> <p>22 keep going.</p> <p>23 BY MR. HALPER:</p> <p>24 Q I'm not trying to cut you off.</p>

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<p style="text-align: right;">181</p> <p>1 A No.</p> <p>2 Q If there's more, I'm happy to hear it.</p> <p>3 A No, no. And I'm trying to get across</p> <p>4 the fact that we make judgments about people</p> <p>5 about things, not just based on them, but on the</p> <p>6 circumstances, the context.</p> <p>7 And the context tells me, just as the</p> <p>8 context tells me that Arbe, whatever his</p> <p>9 qualifications or lack of them, is no fool. The</p> <p>10 context also tells me that this is the way a lot</p> <p>11 of researchers behave.</p> <p>12 What I am saying is, also, I don't</p> <p>13 know whether Steve Geis did in the case of class,</p> <p>14 but I am not going to be put in a position of</p> <p>15 saying I have no basis for saying this is how</p> <p>16 researchers do behave.</p> <p>17 Q Fair enough.</p> <p>18 A That's all I'm saying.</p> <p>19 Q I hear you.</p> <p>20 A Yeah. I didn't want to be forced in a</p> <p>21 peculiar position.</p> <p>22 Q Okay, and I thought, but maybe I</p> <p>23 didn't do a good enough job, that I changed my</p> <p>24 question.</p>	<p style="text-align: right;">183</p> <p>1 THE WITNESS: Thank you. Yeah, Boston</p> <p>2 University, yeah.</p> <p>3 BY MR. HALPER:</p> <p>4 Q Okay, how do you know of Dr. Wolfe?</p> <p>5 A Because I may have used him as a</p> <p>6 reviewer, I may have read something by him.</p> <p>7 they -- the sort of hot research medical world</p> <p>8 isn't that big, as I'm sure the law is the same,</p> <p>9 you know. All professions are fairly small, and</p> <p>10 I tend to know because either at the New England</p> <p>11 Journal where I was or here, you're in the center</p> <p>12 of a web. I can't answer more than that.</p> <p>13 Q No, that's fine.</p> <p>14 A I wouldn't know him in a crowd.</p> <p>15 Q What is your opinion of his work?</p> <p>16 MR. MONTGOMERY: Object to form.</p> <p>17 THE WITNESS: Well, all I can say is he's</p> <p>18 got a good reputation, and I --</p> <p>19 BY MR. HALPER:</p> <p>20 Q Do you have have any reason to</p> <p>21 question his integrity?</p> <p>22 A None.</p> <p>23 Q Do you have any reason to question the</p> <p>24 quality of his work?</p>
<p style="text-align: right;">182</p> <p>1 A Yeah.</p> <p>2 Q Do you know why Steve Geis did what he</p> <p>3 did in connection with class?</p> <p>4 A No.</p> <p>5 MR. MONTGOMERY: Object to form.</p> <p>6 BY MR. HALPER:</p> <p>7 Q Do you know whether Emilio Arbe knows</p> <p>8 what Steve Geis did in connection with class?</p> <p>9 MR. MONTGOMERY: Object to form.</p> <p>10 THE WITNESS: No.</p> <p>11 BY MR. HALPER:</p> <p>12 Q Do you -- do you know Dr. Wolfe?</p> <p>13 A No.</p> <p>14 Q Do you know of him?</p> <p>15 A He's at BU. I know of him, and as far</p> <p>16 as I remember -- and I haven't looked this up --</p> <p>17 he was at Boston University. Is that right?</p> <p>18 Q It's -- Exhibit 4 is his letter.</p> <p>19 A Yeah. As a matter of fact, I knew his</p> <p>20 name well enough, and he's a GI person. And I'd</p> <p>21 totally forgotten until just now that he had a</p> <p>22 co-author written with him.</p> <p>23 MR. NELSON: (Tendering document to</p> <p>24 witness).</p>	<p style="text-align: right;">184</p> <p>1 A None.</p> <p>2 Q In fact, his reputation is good,</p> <p>3 correct?</p> <p>4 A Yes.</p> <p>5 Q If you could turn to Exhibit 3, which</p> <p>6 is the JAMA publication of class, and if you look</p> <p>7 on the second page, I'm going to direct you to a</p> <p>8 sentence under "Study Protocol".</p> <p>9 A Um-hum.</p> <p>10 Q And Mr. Montgomery read it to you, but</p> <p>11 I'll read it again. "After a baseline visit,</p> <p>12 follow-up clinic visits took place at weeks 4,</p> <p>13 13, and 26 after the initial dose of medication,</p> <p>14 and every 13 weeks thereafter. All patients were</p> <p>15 provided an opportunity to complete a minimum of</p> <p>16 6 months of treatment." Do you see that?</p> <p>17 A I certainly do.</p> <p>18 Q Okay. Doesn't that indicate that data</p> <p>19 was collected for more than six months?</p> <p>20 A You -- yes. And you heard me hiccup</p> <p>21 when you read it. In fact, my eyes bulged.</p> <p>22 Q And why?</p> <p>23 A For two reasons. One, it seems to</p> <p>24 indicate that there were more data and nobody</p>

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<p>185</p> <p>1 could have noticed, and two, why was it buried</p> <p>2 there?</p> <p>3 So it makes me -- this is very sad,</p> <p>4 isn't it? Why isn't it here? Why isn't that one</p> <p>5 of the main findings? Why is that not reported?</p> <p>6 Why is it apparently just there? I don't know if</p> <p>7 it's more.</p> <p>8 Q But it does disclose, does it not,</p> <p>9 that the study ran for more than six months --</p> <p>10 A Yes.</p> <p>11 Q -- and data was collected for more</p> <p>12 than six months?</p> <p>13 A Yes.</p> <p>14 Q Both those things are disclosed,</p> <p>15 correct?</p> <p>16 A It discloses that the protocol says</p> <p>17 that they should be, that's what. And so -- and</p> <p>18 what I haven't had time since then is to check</p> <p>19 that there were absolutely no data. You see</p> <p>20 adverse effects during the six month treatment</p> <p>21 period, and that was the crucial thing here,</p> <p>22 wasn't it? At six month, six month, six month.</p> <p>23 You see, it's like saying, I disclosed</p> <p>24 my number plate by having it tacked under the</p>	<p>187</p> <p>1 Q If you could turn to Exhibit 32, which</p> <p>2 is the Juni editorial --</p> <p>3 MR. NELSON: (Tendering document to</p> <p>4 witness).</p> <p>5 THE WITNESS: Thank you.</p> <p>6 BY MR. HALPER:</p> <p>7 Q Are you with me?</p> <p>8 A Yes, thank you.</p> <p>9 Q Okay. Well, before we get to that,</p> <p>10 we've talked about the fact that the full study</p> <p>11 data was posted on the FDA website in February</p> <p>12 2001; isn't that right?</p> <p>13 MR. MONTGOMERY: Object to form.</p> <p>14 THE WITNESS: I believe -- I can't say</p> <p>15 whether it was February, you know, I don't</p> <p>16 remember, but we certainly talked about that,</p> <p>17 yes. I take -- I take your word for it. I don't</p> <p>18 know.</p> <p>19 BY MR. HALPER:</p> <p>20 Q In 2001 --</p> <p>21 A Yeah.</p> <p>22 Q -- at some point, the full dataset --</p> <p>23 A Yeah.</p> <p>24 Q -- was posted --</p>
<p>186</p> <p>1 bottom of my sump pump, you know. It's not --</p> <p>2 that's not how you do it. And it's there in the</p> <p>3 protocol, apparently, but where is it in the</p> <p>4 important places? This (indicating) is what most</p> <p>5 people read, like 90%. Where is it in the</p> <p>6 results? So I'd say, no, it's not properly</p> <p>7 disclosed.</p> <p>8 Q Let's take it in small bites. The</p> <p>9 statement I read to you, you would agree,</p> <p>10 discloses that the study ran for longer than six</p> <p>11 months?</p> <p>12 A That it does, and I've acknowledged</p> <p>13 that.</p> <p>14 Q And you would agree with me that the</p> <p>15 statement I read discloses that data was</p> <p>16 collected for more than six months, correct?</p> <p>17 A Yes.</p> <p>18 Q Okay, those are my only two questions</p> <p>19 right now.</p> <p>20 A Yeah.</p> <p>21 Q Do you have a reason to conclude that,</p> <p>22 based on six months of data, anything in this</p> <p>23 publication is inaccurate?</p> <p>24 A No.</p>	<p>188</p> <p>1 A Yeah.</p> <p>2 Q -- on the FDA website --</p> <p>3 A Yeah.</p> <p>4 Q -- is that right?</p> <p>5 A Yeah.</p> <p>6 MR. MONTGOMERY: Object to form.</p> <p>7 BY MR. HALPER:</p> <p>8 Q And do you recall that --</p> <p>9 A I believe so, yeah, yeah. You and I</p> <p>10 have gone to and fro. I can't remember what</p> <p>11 exactly was on there, you know.</p> <p>12 Q Well, do you recall that the FDA</p> <p>13 posted the full dataset in connection with</p> <p>14 Advisory Committee hearings?</p> <p>15 MR. MONTGOMERY: Object to form.</p> <p>16 THE WITNESS: No, not particularly.</p> <p>17 BY MR. HALPER:</p> <p>18 Q Do you re -- when the FDA -- when --</p> <p>19 I'll withdraw that.</p> <p>20 When the full dataset was posted on</p> <p>21 the FDA website, what information in fact was</p> <p>22 disclosed?</p> <p>23 MR. MONTGOMERY: Object to form.</p> <p>24 THE WITNESS: Well, I -- I've told you I</p>

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<p>189</p> <p>1 can't remember.</p> <p>2 BY MR. HALPER:</p> <p>3 Q Okay, if you look at the Juni article,</p> <p>4 the second page --</p> <p>5 A Uh-huh.</p> <p>6 Q -- do you see the first full paragraph</p> <p>7 says, "Two issues cause concern", and then</p> <p>8 there's a "firstly"?</p> <p>9 A Yes.</p> <p>10 Q And that continues down through the</p> <p>11 end of that paragraph?</p> <p>12 A Yes.</p> <p>13 Q Do you know one way or the other</p> <p>14 whether anything in this section of the Juni</p> <p>15 editorial is -- was not already contained in the</p> <p>16 FDA website postings?</p> <p>17 MR. MONTGOMERY: Object to form.</p> <p>18 THE WITNESS: No, I didn't -- I didn't</p> <p>19 check.</p> <p>20 BY MR. HALPER:</p> <p>21 Q So, for all you know, everything in</p> <p>22 here could have already been disclosed on the FDA</p> <p>23 website --</p> <p>24 MR. MONTGOMERY: Object to form.</p>	<p>191</p> <p>1 protocol that was established before they were</p> <p>2 begun?</p> <p>3 A No.</p> <p>4 Q All right.</p> <p>5 A But -- no. No is the answer.</p> <p>6 Q Okay, would you please look at the</p> <p>7 slides that you prepared, Exhibit 42?</p> <p>8 A Yes.</p> <p>9 MR. NELSON: (Tendering document to</p> <p>10 witness).</p> <p>11 THE WITNESS: Thank you.</p> <p>12 BY MR. MONTGOMERY:</p> <p>13 Q All right, would you please turn to</p> <p>14 the third page?</p> <p>15 A (Witness so doing).</p> <p>16 Q And on that page is an excerpt of the</p> <p>17 Silverstein letter to JAMA; is that correct?</p> <p>18 A Right.</p> <p>19 Q All right, in the middle of the first</p> <p>20 column, do you see the part that you highlighted</p> <p>21 beginning "In retrospect"?</p> <p>22 A Yes.</p> <p>23 Q I'm going to read it into the record.</p> <p>24 "In retrospect, we acknowledge that we could have</p>
<p>190</p> <p>1 BY MR. HALPER:</p> <p>2 Q (Continuing) -- isn't that right?</p> <p>3 A Could be.</p> <p>4 MR. HALPER: No further questions right</p> <p>5 now.</p> <p>6 MR. MONTGOMERY: Okay. It really is just a</p> <p>7 couple.</p> <p>8 REDIRECT EXAMINATION</p> <p>9 BY MR. MONTGOMERY:</p> <p>10 Q Okay, Exhibit 3, the JAMA article that</p> <p>11 you were just talking about, do you have that?</p> <p>12 A Got it.</p> <p>13 Q If you'd look at the second page that</p> <p>14 you were looking at before where it says "Study</p> <p>15 Protocol"?</p> <p>16 A Yeah.</p> <p>17 Q What is a study protocol?</p> <p>18 A The protocol is, This is what we're</p> <p>19 going to do.</p> <p>20 Q Is --</p> <p>21 A And it can be huge, it can be narrow,</p> <p>22 it's often debated very strongly, and it sets</p> <p>23 out, goes through many iterations.</p> <p>24 Q Do clinical studies always follow the</p>	<p>192</p> <p>1 avoided confusion by explaining to the JAMA</p> <p>2 editors why we chose to inform them only of the</p> <p>3 six month analyses and not the longer term data</p> <p>4 that were available to us when we submitted the</p> <p>5 manuscript. We submitted only this information</p> <p>6 because the authors believed the six month data</p> <p>7 were the most scientifically and clinically</p> <p>8 valid. The data after six months were so</p> <p>9 confounded as to be difficult to interpret for</p> <p>10 assessing a drug-related causal GI toxicity."</p> <p>11 Do you see that?</p> <p>12 A Yes.</p> <p>13 Q Did you believe at the time this was</p> <p>14 published that it was an adequate explanation</p> <p>15 for the authors' conduct who wrote the JAMA</p> <p>16 article?</p> <p>17 MR. HALPER: Objection, foundation.</p> <p>18 THE WITNESS: No.</p> <p>19 BY MR. MONTGOMERY:</p> <p>20 Q And why is that?</p> <p>21 A I guess I -- I guess I like people to</p> <p>22 be -- I've climbed all my life. I like people to</p> <p>23 be forthright, really forthright. Silly me.</p> <p>24 Q In your opinion, is the quotation I</p>



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<p style="text-align: right;">193</p> <p>1 just read into the record not fully forthright?</p> <p>2 A I don't like -- and I'm not alone in</p> <p>3 this amongst the JAMA editors -- "we acknowledge</p> <p>4 that we could have avoided confusion." We didn't</p> <p>5 just goof, we kept from you important</p> <p>6 information.</p> <p>7 "Because the authors believe the six</p> <p>8 month data," et cetera, "the data after six</p> <p>9 months was so confounded as to be difficult to</p> <p>10 interpret." Our job is to interpret data. We</p> <p>11 found that offensive. I found it offensive,</p> <p>12 rather. I don't --</p> <p>13 Q Is there any other reason that you</p> <p>14 found this explanation insufficient?</p> <p>15 A Well, I've already said that we're</p> <p>16 dealing with drugs that are taken by old crocks</p> <p>17 who can't do their buttons up, myself, for</p> <p>18 example, and so that means years. And so it's a</p> <p>19 very serious matter when you halve the length of</p> <p>20 a trial. I find it inadequate.</p> <p>21 Q And just to make sure I understand</p> <p>22 what you just said, is that because the people</p> <p>23 taking the medications will often be taking it,</p> <p>24 Celebrex in this case --</p>	<p style="text-align: right;">195</p> <p>1 me, I've been up a long time.</p> <p>2 I can't remember what about -- if</p> <p>3 there was something odd about the statistical</p> <p>4 analysis, and I just can't remember now. I</p> <p>5 haven't looked this up again.</p> <p>6 Q And when you said "those" in your</p> <p>7 previous answer, were you referring to the items</p> <p>8 listed on the second page of Exhibit 42?</p> <p>9 A Right, right.</p> <p>10 Q Okay, I just have a couple questions</p> <p>11 about the book that you were talking about</p> <p>12 earlier. Is it correct that you said you have</p> <p>13 published a book concerning how to conduct</p> <p>14 clinical trials?</p> <p>15 A No, not how to conduct them. I'd</p> <p>16 never do that because I'm not the expert, and I</p> <p>17 know a bunch of people who've written them. In</p> <p>18 fact, I stayed last week with one of them.</p> <p>19 But on the how to -- most doctors,</p> <p>20 like about 99%, can't interpret a study at all,</p> <p>21 and this book is how to interpret every sort of</p> <p>22 study, put yourself in control of the stuff you</p> <p>23 can't understand.</p> <p>24 Q I see.</p>
<p style="text-align: right;">194</p> <p>1 A Well, look it --</p> <p>2 Q -- for longer than six months?</p> <p>3 A Now, I'm just saying -- I'm saying</p> <p>4 this, that it's always problematic and sponsors</p> <p>5 have -- the manufacturers have a tremendously</p> <p>6 difficult problem here, how long to do a trial</p> <p>7 and in who.</p> <p>8 And it's very important for a trial</p> <p>9 like this -- we're not talking about the</p> <p>10 immediate results of somebody who's had a</p> <p>11 myocardial infarct, a heart attack. We're</p> <p>12 talking about something that they'll have to take</p> <p>13 for years if it's any good. With luck, it will</p> <p>14 be. So it really matters if people take it six</p> <p>15 months in the trial or a year in the trial. So</p> <p>16 that's a problem that I thought made this all</p> <p>17 worse, and I wasn't alone in that.</p> <p>18 Q Did you have any other reasons for</p> <p>19 finding this explanation insufficient?</p> <p>20 A Well, I spread out they should have</p> <p>21 dealt with all those (indicating), I think, but I</p> <p>22 haven't checked off to find out if they were</p> <p>23 laughing and -- for the trial duration -- of</p> <p>24 the -- I can't remember what it was, and forgive</p>	<p style="text-align: right;">196</p> <p>1 A And that's why it's called The Users</p> <p>2 Guides, and it's now become very fat and very</p> <p>3 popular.</p> <p>4 MR. NELSON: But you haven't made a penny</p> <p>5 out of it.</p> <p>6 THE WITNESS: But you've made tons of money</p> <p>7 from it.</p> <p>8 MR. NELSON: There we go.</p> <p>9 BY MR. MONTGOMERY:</p> <p>10 Q Is it generally directed towards</p> <p>11 clinicians?</p> <p>12 A Yes. The idea is to -- for physicians</p> <p>13 to -- to take control of -- to understand what it</p> <p>14 is they're reading because this is sophisticated</p> <p>15 stuff, some of it. It should be.</p> <p>16 Q And do you have any idea how many</p> <p>17 copies of the book have been distributed?</p> <p>18 A I don't know, about 40,000 or</p> <p>19 something like that. I mean it's not that great.</p> <p>20 Q And is it -- has it been issued</p> <p>21 through JAMA?</p> <p>22 A No, it was issued through the AMA</p> <p>23 Press. The publisher's going to -- that's -- so</p> <p>24 it's had zero publi -- zero -- now, you asked --</p>

Drummond, Rennie 1/18/2007 1:30:00 PM

<p>197</p> <p>1 zero publicity. It's just sold itself.</p> <p>2 MR. MONTGOMERY: All right, I have no</p> <p>3 further questions.</p> <p>4 MR. HALPER: No questions.</p> <p>5 MR. NELSON: I have no questions.</p> <p>6 MR. MONTGOMERY: We will end the deposition</p> <p>7 at this time.</p> <p>8 THE VIDEOGRAPHER: This is the end of the</p> <p>9 deposition. This is the end of Tape 5. The time</p> <p>10 is 6:26 p.m. The running time of this tape is</p> <p>11 28 minutes and 57 seconds.</p> <p>12 WHEREUPON, FURTHER DEPONENT SAYETH NOT</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>199</p> <p>1 STATE OF ILLINOIS )</p> <p>2 ) ss:</p> <p>3 COUNTY OF COOK )</p> <p>4 I, Deborah Habian, a Certified</p> <p>5 Shorthand Reporter within and for the State of</p> <p>6 Illinois, do hereby certify:</p> <p>7 That previous to the commencement of the</p> <p>8 examination of the witness, the witness was duly</p> <p>9 sworn to testify the whole truth concerning the</p> <p>10 matters herein;</p> <p>11 That the foregoing deposition was reported</p> <p>12 stenographically by me, was thereafter reduced to</p> <p>13 printed transcript by me, and constitutes a true</p> <p>14 record of the testimony given and the proceedings</p> <p>15 had;</p> <p>16 That the said deposition was taken before</p> <p>17 me at the time and place specified;</p> <p>18 That the reading and signing by the</p> <p>19 witness of the deposition transcript was agreed</p> <p>20 upon as stated herein;</p> <p>21 That I am not a relative or employee</p> <p>22 of attorney or counsel, nor a relative or</p> <p>23 employee of such attorney or counsel for any of</p> <p>24 the parties hereto, nor interested directly or indirectly</p> <p>in</p> <p>the outcome of this action.</p> <p>IN WITNESS WHEREOF, I do hereunto set my</p> <p>hand this ____ day of _____, 2007.</p> <p>DEBORAH HABIAN, CSR, RMR, CRR</p> <p>Notary Public</p> <p>CSR No. 084-022432</p>
<p>198</p> <p>1 IN THE UNITED STATES DISTRICT COURT</p> <p>2 DISTRICT OF NEW JERSEY</p> <p>3 ALASKA ELECTRICAL PENSION FUND, )</p> <p>4 et. al., )</p> <p>5 Plaintiffs, )</p> <p>6 vs. ) No. 03-1519</p> <p>7 PHARMACIA CORPORATION, et. al., )</p> <p>8 Defendants. )</p> <p>9</p> <p>10</p> <p>11 I hereby certify that I have read the</p> <p>12 foregoing transcript of my deposition given at</p> <p>13 the time and place aforesaid, consisting of pages</p> <p>14 1 to 197, inclusive, and I do again subscribe and</p> <p>15 make oath that the same is a true, correct, and</p> <p>16 complete transcript of my deposition so given as</p> <p>17 aforesaid and includes changes, if any, so made</p> <p>18 by me.</p> <p>19</p> <p>20 _____</p> <p>21 DR. DRUMMOND RENNIE</p> <p>22 SUBSCRIBED AND SWORN TO</p> <p>23 before me this ____ day</p> <p>24 of _____, A.D. _____.</p> <p>Notary Public</p>	

# EXHIBIT 11

From: LEFKOWITH, JAMES B. [PHR/1825]  
Sent: Friday, September 08, 2000 8:56 AM  
To: ARBE, EMILIO [PHR/5430]  
Subject: RE: CLASS Data

Emilio-

I think that it might be a good idea for you to discuss your concerns with me directly before making any more statements regarding the issues that concern you. I believe that you do not fully understand the data and the analysis.

Jim Lefkowitz

-----Original Message-----

From: ARBE, EMILIO [PHR/5430]  
Sent: Friday, September 08, 2000 6:57 AM  
To: SHIELD, MICHAEL J [PHR/5430]; JADERBERG, MAGNUS [PNU/GBMKEPO1];  
FORREST, DAVID [PNU/GBMKEPO1]  
Cc: LEFKOWITH, JAMES B. [PHR/1825]; HAMELIN, PAUL R. [1820]  
Subject: RE: CLASS Data

The results I quote are lifted from the study report. I will double-check that all the figures are correct and I haven't made any gross misinterpretations. Emilio

-----Original Message-----

From: SHIELD, MICHAEL J [PHR/5430]  
Sent: Thursday, September 07, 2000 8:23 AM  
To: JADERBERG, MAGNUS [PNU/GBMKEPO1]; FORREST, DAVID [PNU/GBMKEPO1]  
Cc: LEFKOWITH, JAMES B. [PHR/1825]; HAMELIN, PAUL R. [1820]; ARBE,  
EMILIO [PHR/5430]  
Subject: RE: CLASS Data

EXHIBIT

28

1.12.07 05

Magnus,

I haven't seen these data presented in this way before so I cannot judge properly the validity of what Emilio is stating. I would agree that the analyses reported in JAMA are not exactly as stated in the original protocol. There are though I understand from the R&D group good reasons for what has been done. In my notes from the presentation made here last week by Jim Lefkowitz I see that he used the term "refined" as applied to the subsequent data analyses. The six months issue, as explained by Jim was to set a point which all patients had completed (taking into account earlier withdrawals up to that time). I don't know whether you were at the EULAR conference (June 2000) but if you were and attended the Searle/Pfizer symposium then you would have heard the considerable debate there was re what constituted "intent-to-treat". In a true "intent-to-treat" there is actually a need to follow-up ALL patients for the ENTIRE treatment period (whatever period is defined) whether or not they have withdrawn from the original test medications. In practice this is rarely done and these debates about "intent-to-treat" are largely semantic ones. In the real world one wants to know, beyond reasonable doubt, whether or not a treatment produces a desired effect and whether or not there are undesirable effects of any consequence.

Emilio's statements that there are no differences between Celebrex and the comparator NSAIDs re serious GI events I find somewhat surprising, and as indicated above I haven't seen the data portrayed in this way before. From what I have seen I am satisfied that in the non-aspirin group (which comprises almost 80% of the patients treated and which is comparable to the VIGOR study in the sense that patients in the Merck study did not use aspirin, except by protocol violation) that we have a statistically significant outcome for Celebrex versus Ibuprofen and Diclofenac. When combining the results for both NSAIDs one does not see statistically significant differences for Celebrex vs NSAID in the aspirin taking population. My only comments about that are twofold. First, that is what one would expect in that Celebrex doesn't have any protective effect against aspirin (unlike say the misoprostol component in Arthrotec) so I would expect to see exactly the same sort of result in takers of a drug like paracetamol which as far as we know is non-GI damaging. The second point is that I believe our data is actually better than we have currently

presented in the public domain in that when one looks at the separate NSAIDs there is a greater GI-event rate on diclo+aspirin than on celebrex+ aspirin. This, I believe, is readily explicable in terms of the differing pharmacodynamic effects of celebrex and diclofenac on platelet function (beneficial towards Celebrex). This, though, I am happy to set to one side as the R&D folks have done to save unduly complicating the message, though in doing so we do lose to some extent a potential advantageous point.

Consequently in summary re the GI event rates everything I have seen demonstrates, to me at least, that we have clear separation of celebrex from diclo and ibuprofen. The Kaplan-Maier plots which take into account differential exposure times show that very elegantly.

Re the tolerability profile I think it has to be stressed, from the outset, that the CLASS study was never intended to be other than a study to focus on whether or not the drug retained COX-2 specificity CLINICALLY and to demonstrate that it was decided (in fact demanded by the FDA) that twice the maximum therapeutic dose should be used. Consequently if one does obtain reasonable tolerability at this dose that in itself would be remarkable given that no NSAID can be used at twice its maximum therapeutic dose without causing SEVERE intolerance (e.g what tolerability profile would you expect to see at 300mg/day of diclofenac). Consequently an overall GI symptom profile for Celebrex 800mg/day which was unquestionably better (statistically so) than diclofenac at 150mg/day and which was virtually the same seen with ibuprofen has I think to be regarded as a good result. Additionally re both diclo and ibuprofen Celebrex demonstrated, at this dose, a better profile re biochemistry (LFTs and renal) and on BP and on potential to cause anaemia as detected by Hb changes.

Emilio's point re rash really singles out one item that is very readily dismissed. To take the incidence of rash in the CLASS study as an indicator of tolerability appears to me to be erroneous for the following reasons. As pointed out in the original Integrated Safety Summary (ISS) prepared for registration submissions by R&D (page 332, document N49-98-07-819) and as is reflected in the "Skin" adverse events section (p243/4) of the "Celecoxib Clinical Summary" which I wrote for the EU submission, celecoxib demonstrates a dose-related increase in rash. This is distinct from the LACK of dose response seen, with celecoxib, as far as I am aware, for any other adverse event. The ISS on page 332 states: "There was an increase in incidence of rash at higher celecoxib doses, with the maximal incidence of 3.4% associated with the 400mg BID dose, thus suggesting a dose-response relationship". Emilio certainly has access to, and I thought had seen, both of these documents. If the mechanism, which as yet is unknown, is exposure-duration related then obviously in longer studies at high dose (above the therapeutic dose currently recommended) the incidence will increase. As pointed out above, the CLASS study was not there to examine the overall side effect profile of celecoxib. That was very satisfactorily done in the registration studies. The findings re rash in the CLASS study merely confirm what we already know about the product. I have no hesitation in recommending that on this basis we can focus on the GI-event rates from CLASS without having to focus on the other findings for the reasons stated. The TOLERABILITY PROFILE and other ADE profile from the extensive database we have at therapeutic doses is perfectly satisfactory, and in fact is better than the CLASS data, for our medical & marketing colleagues to use to demonstrate our superiority over NSAIDs. (I made the latter point at last week's UK marketing meeting with Jim Lefkowitz).

I am a great believer in such discussion points being out in the open and also in encouraging people to raise their issues so that they can be addressed. Consequently I think it is only fair that Jim Lefkowitz should have the opportunity to see and respond to Emilio's points since Jim has lived with and breathed the CLASS data over the past several months and has seen the data in much greater depth than me - hence I have copied Jim on this reply to you Magnus. In that way hopefully we can focus on the facts and see exactly where the truth lies. I would hope that in this process discussion can be held without any parties personalising the discussion. A lack of objectivity is always dangerous.

Regards  
Michael

—Original Message—

From: JADERBERG, MAGNUS [PNU/GBMKEPO1]

Sent: 07 September 2000 05:01

To: SHIELD, MICHAEL J [PHR/5430]; FORREST, DAVID [PNU/GBMKEPO1]

Subject: CLASS Data

Please see Emilio's comments below - any comments from Michael who has followed this study from the beginning?

The rest of us have a lot to catch up on and so not that easy to advice Emilio although it is clearly of concern to hear someone on 'the inside' express these views.  
Magnus

---

Forward Header

Subject: CLASS Data  
Author: EMILIO ARBE at Exchange  
Date: 04/09/2000 10:19

Dear Magnus,

Since you brought up the subject this morning, here is what I think about CLASS. The study was set out to demonstrate that based on a withdrawal rate of up to 35%, patients would experience clinically significant UGI adverse events at a rate of 0.3% per year with SC-58635 and 1.2% per year with NSAIDs as a group. The protocol did not specify that the endpoint would be assessed at 6 months only. An interim analysis was planned, but this was only to make sure that enough events had occurred so that the differences would be statistically significant by the end of the study, which was 12 months.

There are several flaws in the way that we present the data. We claim that we cannot compare the groups at 12 months because the drop out rate was so much higher in the diclofenac group. In fact at 26.5 % it was lower than expected and not that different from celecoxib with 22.4% and ibuprofen 23%. The total number of events required, which was 37, was actually met as there were 38 in total, 17 with celecoxib, 10 with diclofenac and 11 with ibuprofen. Considering that twice as many patients had been treated with celecoxib, this equated to annual rates of 0.43%, 0.50% and 0.55% percent. None of the differences were statistically significant. If one looks at the subset of patients who did not take aspirin, which we so much publicise, the rates were 0.26%, 0.26% and 0.64%, again with no statistically significant differences.

With a bit of data massage, what Steve Geis and his team have done is to focus on the 6 month data, for no other reason that it happens to look better, and this time they concentrate on the non aspirin treated patients, and ignore the fact that at no time interval did we see a statistically significant difference with diclofenac, whether one looks at patients taking aspirin or not, at 6 or at 12 months. Unfortunately, UK doctors would only be interested in looking at the rate of GI events with diclofenac since such a high dose of ibuprofen is rarely used.

In terms of tolerability the results are also disappointed, in that the rates of withdrawal due to dyspepsia were 3.8%, 4.4% and 3.9% for celebrex, diclofenac and ibuprofen. To top up the lot we had a 6.2% of rash, which was statistically significantly greater to that seen for the diclofenac and ibuprofen groups. So much for our delivering lasting control in arthritis claim based on improved tolerability and safety profiles.

In my opinion though, these results do not say much about Celebrex used at therapeutic doses, and hence our interest in collecting some more meaningful data through a SAMM study. Probably then, the annual complication rate is 0.3%

as expected and there is probably a tolerability advantage as seen in the Emery study, celebrex 200 mg bid vs diclofenac 75 mg bid over 6 months in RA.

The point I am trying to make though is that I don't see what is so great about CLASS. Personally I find it bizarre that we would want to roll out the data to opinion leaders who aren't necessarily dupe and I wouldn't feel too comfortable presenting a fudged version of the facts. Any guidance from your side is of course welcome.

Kind regards,

Emilio

# EXHIBIT 12



From: Wahba, Mona M  
Sent: Tuesday, May 22, 2001 5:17 PM  
To: Cristo, Stephen  
Subject: CBX-0234902\_FW: CLASS manuscripts for review: Urgent attention required

Importance: High

Follow Up Flag: Follow up  
Due By: Monday, May 21, 2001 12:00 PM  
Flag Status: Flagged



CBX-0234903\_CELEC  
CBX-0234904\_COX-CBX-0234905\_CLAS  
COXIB CV ver2.... 2 Inhibitor Up... S manuscript 2...

fyi

-----Original Message-----

From: Wahba, Mona M  
Sent: Monday, May 21, 2001 2:03 PM  
To: Denton, James; Harris, Andrew; Silber, Beth Ann; Pettitt, Dan;  
Sirota, Eric; Bahrt, Kenneth; Shafner, Lori S; Fletcher, Mark P; Cary,  
Meg; Gavigan, Michael; Gandelman, Mitchell; McElwee, Newell  
Subject: FW: CLASS manuscripts for review: Urgent attention required  
Importance: High

Dear All,

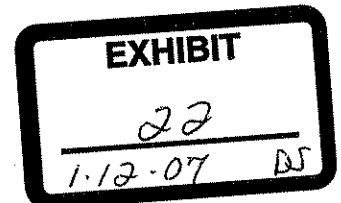
Please see my comments attached, i'd recommend to refer to the  
conclusions of the second attachment in the CVS ms.

In my opinion, the GI ms is apologetic, weak and not convincing, since  
cx did not show statistical difference from Diclo even using the  
combined endpoint. We are also cherry picking the data ( using 6 m as  
study duration).

There is a need to sharpen the story around the effect of GI withdrawals  
in the diclo group and the effect of ASA as a confounding factor on the  
expanded endpoint if we decide to publish this ms.

Do we have the newly created tables supporting these 2 ms to QA the #s?

Mona M. Wahba, M.D.  
Pfizer Global Research and Development  
Office: 860 441 8950  
Mobile: 860 625 9356  
Fax: 860 715 8463  
<mailto:mona\_m\_wahba@groton.pfizer.com>



-----Original Message-----

From: Denton, James  
Sent: Sunday, May 20, 2001 5:36 PM  
To: Sadosky, Alesia; Byer, Alicia; Harris, Andrew; Silber, Beth Ann;  
Prestel, Betina; Pettitt, Dan; Nickerson, David F; Alemayehu, Demissie;  
Shapiro, Elyse R; Sirota, Eric; Lee, Fleur; Ancona, Frank; Cawkwell,  
Gail; Lymburner, Jeffrey; Plofchan, Jennifer N; Goldman, Jonathan;  
Dicker, Joy; Bahrt, Kenneth; Levy, Lisa; Shafner, Lori S; Fletcher, Mark  
P; Horn, Mark; Cary, Meg; Gavigan, Michael; Gandelman, Mitchell; Wahba,  
Mona M; McElwee, Newell; Sobel, Rachel; Reynolds, Robert; Nelson,

Rooney; Miller, Tina; Quinn, Tricia; Leishman, Valarie  
Subject: FW: CLASS manuscripts for review: Urgent attention required

Please forward comments to Beth and me by Wednesday May 23.  
Jim

-----Original Message-----

From: Cornick, David [mailto:dcornick@hbase.com]  
Sent: Thursday, May 17, 2001 4:01 AM  
To: Fort, John; Denton, James; 'Tim Walbert'  
Cc: Markind, Jan E; 'Jim Lefkowitz'; Donovan, Dan  
Subject: CLASS manuscripts for review: Urgent attention required  
Importance: High

Dear All,

Please find attached two draft CLASS manuscripts (GI and CV) from Jim Lefkowitz's group. I would appreciate it if you could review the attached documents and return your comments to Jan Markind and I by Thursday 24th May at the latest.

Jim, I would very much appreciate it if you could consolidate all the Pfizer comments into one e-mail prior to returning them to Jan and I. Many thanks for your help.

Look forward to hearing from you all in due course

Regards

Dave Cornick  
Editorial Leader  
PPS International Communications  
Phone +44 (0)1903 288131  
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-----Original Message-----

From: MARKIND, JAN E [GPB/1820] [mailto:jan.e.markind@pharmacia.com  
<mailto:jan.e.markind@pharmacia.com> ]  
Sent: 17 May 2001 02:20  
To: 'Cornick, David'  
Subject: FW:  
Importance: High

Dave,

Please send out for review to Jim Denton, John Fort, and Tim Walbert. Please ask Pfizer to consolidate all comments for each manuscript into 1 e-mail. Please use the abstracts from these as we discussed; alter as needed.

Thanks,

Jan

-----Original Message-----

From: LEFKOWITH, JAMES B. [PHR/1825]  
Sent: Wednesday, May 16, 2001 8:56 AM  
To: MARKIND, JAN E [GPB/1820]  
Subject:

Jan-  
Please distribute these draft copies to the Publication Team. I would  
like  
to limit the review process to 7 business days.  
JL

# EXHIBIT 13

Fred Silverstein

September 29, 2010

1

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

ALASKA ELECTRICAL PENSION FUND,  
  
  
Plaintiff  
  
vs.  
  
PHARMACIA CORP., et al.,  
  
  
Defendants.

VIDEOTAPED DEPOSITION OF FRED SILVERSTEIN, M.D.  
September 29, 2010  
Seattle, Washington

Reported by:  
Connie Recob, CCR, RMR, CRR, CLR  
CCR No. 2631  
Job No. Seattle 161218/San Diego 335512

2

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3

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Also Present:  
Steve Ewing, Videographer  
  
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MR. WEISS228  
MR. MONTGOMERY252  
  
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Exhibit 193 12/21/83 Letter, Bates Nos. DEFS  
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00374 through 00375 14



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Fred Silverstein

September 29, 2010

<p>1 EXHIBIT INDEX CONTINUED</p> <p>2</p> <p>3 EXHIBIT NO. DESCRIPTION PAGE NO.</p> <p>4 Exhibit 207 Rational for Publishing the CLASS 6</p> <p>Month Data, Bates Nos. Silverstein</p> <p>5 00115 through 00123 210</p> <p>6 Exhibit 208 e-mail, Bates No. Silverstein 00077 213</p> <p>7 Exhibit 209 handwritten notes, Bates Nos.</p> <p>Silverstein 00090 through 00094 214</p> <p>8</p> <p>9 Exhibit 210 Letter, Bates Nos. Silverstein 00128</p> <p>through 00134 215</p> <p>10 Exhibit 211 Handwritten Notes, Bates Nos.</p> <p>Silverstein 00124 through 00127 219</p> <p>11</p> <p>12 Exhibit 212 Handwritten Notes, Bates Nos.</p> <p>Silverstein 00080 through 00082 224</p> <p>13</p> <p>14 WITNESS INSTRUCTED NOT TO ANSWER</p> <p>15</p> <p>16 (None)</p> <p>17</p> <p>18 INFORMATION REQUESTED</p> <p>19</p> <p>20 (None)</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 Rice for the plaintiffs.</p> <p>2 MR. WEISS: Josh Weiss, Cadwalader,</p> <p>3 Wickersham &amp; Taft for the defendants.</p> <p>4 MS. McPHEE: Joan McPhee for Dr. Fred</p> <p>5 Silverstein.</p> <p>6 MR. BUSHOFSKY: And Jeff Bushofsky from</p> <p>7 Ropes &amp; Gray also for the witness.</p> <p>8</p> <p>9 FRED SILVERSTEIN, M.D., having been first duly sworn,</p> <p>10 deposed and testified as</p> <p>11 follows:</p> <p>12</p> <p>13 EXAMINATION</p> <p>14 BY MR. MONTGOMERY:</p> <p>15 Q. Could you state your name and home address for the record,</p> <p>16 please?</p> <p>17 A. Fred Eli Silverstein. My home address is 1246 15th Avenue</p> <p>18 East, Seattle, Washington 98112.</p> <p>19 Q. Have you ever been deposed before, Dr. Silverstein?</p> <p>20 A. I have not.</p> <p>21 Q. Okay. In that case I'll run over a few ground rules.</p> <p>22 A. Thank you.</p> <p>23 Q. I'm going to ask you a series of questions which hopefully</p> <p>24 you'll be able to answer. The attorneys over here may</p> <p>25 interpose objections so if they make an objection just wait</p>
<p>1 BE IT REMEMBERED that on Wednesday,</p> <p>2 September 29, 2010, at 1700 Seventh Avenue, Suite 2200,</p> <p>3 Seattle, Washington, at 9:00 a.m., before Connie Recob, CCR,</p> <p>4 RMR, CRR, CLR, appeared FRED SILVERSTEIN, M.D., the witness</p> <p>5 herein;</p> <p>6 WHEREUPON, the following proceedings were</p> <p>7 had, to wit:</p> <p>8</p> <p>9 &lt;&lt;&lt;&lt;&lt;&lt; &gt;&gt;&gt;&gt;&gt;&gt;</p> <p>10</p> <p>11 THE VIDEOGRAPHER: This is Tape No. 1 to</p> <p>12 the videotaped deposition of Dr. Fred Silverstein in the</p> <p>13 matter of Alaska Electrical Pension Fund versus Pharmacia</p> <p>14 Corporation, being heard before the U.S. District Court for</p> <p>15 the District of New Jersey, Case File No. 03-15-19 (AEI).</p> <p>16 This deposition is being held at Tousley Brain Stephens, 1700</p> <p>17 Seventh Avenue, Suite 2200, Seattle, Washington 98101.</p> <p>18 Today's date is September 29th, 2010 and the time is 9:00.</p> <p>19 My name is Steve Ewing and I am the videographer. The</p> <p>20 court reporter is Connie Recob. Counsel, will you please</p> <p>21 introduce yourselves and affiliations and the witness can be</p> <p>22 sworn.</p> <p>23 MR. MONTGOMERY: Matt Montgomery for the</p> <p>24 plaintiffs.</p> <p>25 MR. OLIVER: Lance Oliver with Motley</p>	<p>1 for their objection to get on the record and unless your</p> <p>2 counsel tells you not to answer the question you can then</p> <p>3 answer the question.</p> <p>4 It's important that we don't talk over each other</p> <p>5 because the court reporter here has to type everything we say</p> <p>6 and she can't type two people speaking at the same time.</p> <p>7 Also, it's important that you answer all the questions</p> <p>8 verbally; nodding or uh-huh, huh-uh doesn't translate to the</p> <p>9 record very well but I'll try and remind you and attorneys</p> <p>10 may as well.</p> <p>11 Is there any reason such as illness or medication that</p> <p>12 you can't give your best testimony today?</p> <p>13 A. No.</p> <p>14 Q. All right. I'd like to go over some definitions that will</p> <p>15 hopefully make the rest of the day go more smoothly. Are you</p> <p>16 familiar with a drug called celecoxib?</p> <p>17 A. I am.</p> <p>18 Q. And is that also called Celebrex?</p> <p>19 A. It is.</p> <p>20 Q. All right. Are you familiar with a clinical study called</p> <p>21 CLASS, C-L-A-S-S?</p> <p>22 A. I am.</p> <p>23 Q. And is that also known as Celecoxib Long-Term Arthritis</p> <p>24 Safety Study?</p> <p>25 A. It is.</p>



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<p>9</p> <p>1 Q. Are you comfortable using the initials GI to refer to 2 gastrointestinal? 3 A. I am. 4 Q. Okay. Are you familiar with nonsteroidal anti-inflammatory 5 drugs? 6 A. I am. 7 Q. And are those also referred to as NSAIDs? 8 A. That's correct. 9 Q. Are you familiar with the Journal of the American Medical 10 Association? 11 A. I am. 12 Q. Is that also sometimes referred to as JAMA? 13 A. It is. 14 Q. Are you familiar with a term called "Clinically Significant 15 Upper Gastrointestinal Events"? 16 A. Yes. 17 Q. And are those sometimes referred to as CSUGIEs? 18 A. Yes. 19 Q. How do you pronounce it? 20 A. Well, I don't use that expression. I prefer to use 21 "significant upper GI events." Some people use that acronym 22 and it's not one that I use or am comfortable with. So that 23 one I'd like to avoid and use words. 24 Q. Sure. That's what I'm trying to do this for. 25 A. Right.</p>	<p>11</p> <p>1 (Exhibit No. 191 marked 2 for identification.) 3 Q. (BY MR. MONTGOMERY) Have you seen <u>Exhibit 191</u> before? 4 A. I believe I have. 5 Q. And is it your understanding this is a depo subpoena -- I'm 6 sorry -- a deposition subpoena? 7 A. Yes. 8 Q. Is it your understanding you're here today pursuant to this 9 subpoena? 10 A. Yes. 11 Q. You can just put that to the side. What we're going to do 12 today, as I give you these, you can just stack them up here. 13 A. Okay. 14 Q. There may be some exhibits that I'm going to refer to again 15 later so I'll let you know that and you can maybe put them in 16 a different pile so that they're easier to get. 17 A. Okay. Fair enough. 18 MR. MONTGOMERY: At this point I'd like 19 to ask the court reporter to mark what will be <u>Exhibit 192</u>. 20 (Exhibit No. 192 marked 21 for identification.) 22 Q. (BY MR. MONTGOMERY) Is <u>Exhibit 192</u> a copy of your CV or 23 curriculum vitae? 24 A. That's correct. 25 Q. And is it the most current version?</p>
<p>10</p> <p>1 Q. So what are you comfortable with again? 2 A. Upper GI adverse event, upper GI bleed, upper GI perforation, 3 you know, a little bit more specific. CSUGIEs is kind of a 4 folksy acronym that I don't use. 5 Q. When you say upper GI event, is that the same as a 6 perforation obstruction and bleed or bleed? 7 A. No, not necessarily. In the upper GI tract you can have a 8 significant complication which is usually a bleed, a 9 perforation or obstruction, but you can also have a 10 significant event which is not a complication but which is, 11 for example, a symptomatic ulcer, so somebody who will tell 12 you they have belly pain and they're endoscoped or have an 13 x-ray and they're found to have an ulcer. 14 So generally complications are considered to be 15 bleeding, perforation or obstruction, and the other 16 significant event in that realm would be a symptomatic ulcer. 17 Q. Okay. So can we -- is there a distinction between ulcer 18 complications and a symptomatic ulcer then? 19 A. Yes, there is. I would say there is. 20 Q. And are you comfortable with that terminology? 21 A. Yes, I am. 22 Q. Okay. 23 MR. MONTGOMERY: I'd like to ask the 24 court reporter to mark what will be <u>Exhibit 191</u>. 25 ////</p>	<p>12</p> <p>1 A. It is. 2 Q. And are you currently employed? 3 A. I am not. I'm retired. 4 Q. Okay. Do you do any consulting? 5 A. I do. 6 Q. And do you do any consulting for Pfizer? 7 A. I do not. 8 Q. Have you done any consulting for Pfizer since you retired? 9 A. No, I have not. I retired in about 2005 and I haven't done 10 any consulting for Pfizer since about 2001. 11 Q. Are you at this point in any talks or negotiations to do 12 consulting with Pfizer in the future? 13 A. No. 14 Q. Okay. Would you turn to Bates No. Silverstein 00623 in 15 <u>Exhibit 192</u>? Do you know what Bates numbers are? 16 A. No. 17 Q. They're just the page numbers in the lower right-hand corner. 18 A. Okay. 19 Q. Do you see No. 147 on that page? 20 A. I do. 21 Q. And does that refer to an article you coauthored that was 22 published in JAMA? 23 A. I did. 24 Q. And can we refer to that for the purposes of the deposition 25 as the JAMA article?</p>



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<p>13</p> <p>1 A. Yes.</p> <p>2 Q. Okay.</p> <p>3 MR. MONTGOMERY: I'd like to ask the</p> <p>4 court reporter to mark what will be <u>Exhibit 193</u>.</p> <p>5 (Exhibit No. 193 marked</p> <p>6 for identification.)</p> <p>7 Q. (BY MR. MONTGOMERY) And is <u>Exhibit 193</u> a consulting agreement</p> <p>8 between yourself and Searle?</p> <p>9 A. That's correct.</p> <p>10 Q. And Searle is a pharmaceutical company?</p> <p>11 A. That's correct.</p> <p>12 Q. Is this the first consulting agreement that you think you</p> <p>13 entered into with Searle?</p> <p>14 A. I'm not positive but I think that is the case.</p> <p>15 Q. And after the date of this agreement -- well, first of all</p> <p>16 the date of this agreement is December 31st, 1983; is that</p> <p>17 correct?</p> <p>18 A. That's correct.</p> <p>19 Q. After this agreement did you enter into -- subsequently enter</p> <p>20 into a series of consulting agreements with Searle over the</p> <p>21 years?</p> <p>22 A. Yes.</p> <p>23 MR. MONTGOMERY: I'd like to ask the</p> <p>24 court reporter to mark what will be <u>Exhibit 194</u>. Hold on one</p> <p>25 second.</p>	<p>15</p> <p>1 Pfizer?</p> <p>2 A. I did not.</p> <p>3 Q. After the acquisition did you enter into a consulting</p> <p>4 relationship with Pfizer?</p> <p>5 A. I don't remember. I think that this -- to the best of my</p> <p>6 knowledge this was the last consulting agreement I had with</p> <p>7 Pharmacia and I did not enter into a consulting agreement</p> <p>8 directly with Pfizer, as far as I remember.</p> <p>9 MR. MONTGOMERY: At this point I'd like</p> <p>10 to ask the court reporter to mark what will be <u>Exhibit 195</u>.</p> <p>11 (Exhibit No. 195 marked</p> <p>12 for identification.)</p> <p>13 Q. (BY MR. MONTGOMERY) Could you tell me what <u>Exhibit 195</u> is?</p> <p>14 A. In the process of providing information that was requested as</p> <p>15 part of the subpoena I went back through all of my records,</p> <p>16 spent hours going through -- old tax files is where I found</p> <p>17 this, and attempted to summarize the information I had about</p> <p>18 remuneration I received from Searle and/or Pharmacia from</p> <p>19 1995 through 2004, and 2004 could be 2010 because there's</p> <p>20 been no change. It's been zero since 2002. And this is a</p> <p>21 summary of what I could find.</p> <p>22 Now, in -- about two months ago I was asked to go</p> <p>23 through things again and I did it again and in a</p> <p>24 miscellaneous file that I hadn't looked at previously, of</p> <p>25 course I'm talking about cartons and cartons of tax files, I</p>
<p>14</p> <p>1 (Exhibit No. 194 marked</p> <p>2 for identification.)</p> <p>3 MR. WEISS: Is this two exhibits?</p> <p>4 MR. MONTGOMERY: I'm sorry. There was an</p> <p>5 issue with the copier. I gave you the ones I was trying to</p> <p>6 get rid of.</p> <p>7 Q. (BY MR. MONTGOMERY) Is <u>Exhibit 194</u> a consulting agreement</p> <p>8 between you and Pharmacia dated February 1st, 2002?</p> <p>9 A. Yes.</p> <p>10 Q. Is it your understanding that at some point Searle was</p> <p>11 acquired by Pharmacia?</p> <p>12 A. Yes.</p> <p>13 Q. And at that point did you enter into a consulting</p> <p>14 relationship with Pharmacia?</p> <p>15 A. Yes.</p> <p>16 Q. And were there a number of such agreements over the years?</p> <p>17 A. I don't -- I don't know. That I don't remember. I never</p> <p>18 could really follow what was happening with these</p> <p>19 acquisitions and so -- as far as I know there's this one. I</p> <p>20 don't know if there were any others with Pharmacia and</p> <p>21 there's been nothing recent.</p> <p>22 Q. Is it your understanding that at some point Pharmacia was</p> <p>23 acquired by Pfizer?</p> <p>24 A. That's correct.</p> <p>25 Q. Prior to that acquisition did you do any consulting work for</p>	<p>16</p> <p>1 found some additional data. But nothing that changes any of</p> <p>2 this, it's just background or backup information. There was</p> <p>3 no, to my knowledge, significant new information.</p> <p>4 Q. All right. And to your understanding you never received any</p> <p>5 money directly from Pfizer then?</p> <p>6 A. That's correct.</p> <p>7 Q. Okay. Let's just run through this then.</p> <p>8 So in 1995 is it your understanding you received</p> <p>9 somewhat more than \$35,000 from Searle?</p> <p>10 A. Correct.</p> <p>11 Q. In '96 you received somewhat more than \$37,000 from Searle?</p> <p>12 A. That's correct.</p> <p>13 Q. And in 1997 you received somewhat more than \$68,000 from</p> <p>14 Searle?</p> <p>15 A. That's correct.</p> <p>16 Q. In 1998 did you ever find that information?</p> <p>17 A. I don't -- no.</p> <p>18 Q. Okay. In 1999 you received somewhat more than \$64,000 from</p> <p>19 Searle?</p> <p>20 A. That's correct.</p> <p>21 Q. In 2000 you received \$75,000 from either Searle or Pharmacia?</p> <p>22 A. That's correct.</p> <p>23 Q. And what is the --</p> <p>24 A. Expenses. I just had a separate note that I had \$6,167 for</p> <p>25 expenses.</p>



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<p style="text-align: right;">17</p> <p>1 Q. And that's in addition to the 75 --</p> <p>2 A. In addition to the \$75,000.</p> <p>3 Q. It's important that you let me finish my question before you</p> <p>4 start.</p> <p>5 A. Excuse me.</p> <p>6 Q. I appreciate your willingness to answer, though.</p> <p>7 Okay. In 2001 it's your understanding you received</p> <p>8 slightly more than \$12,000 from Searle or Pharmacia?</p> <p>9 A. That's correct.</p> <p>10 Q. And then beneath that it says 87,000. Do you see that?</p> <p>11 A. Yes, that's correct.</p> <p>12 Q. And what does that refer to?</p> <p>13 A. It's also compensation I received in 2001. And I don't know</p> <p>14 whether the 87,000 encompassed the 12,000. I am not clear.</p> <p>15 I'm not sure about that. But I wanted to report both of them</p> <p>16 because that's what my records had that I received.</p> <p>17 Q. Okay. So in 2001 you either received \$87,000 from Searle --</p> <p>18 A. Right.</p> <p>19 Q. -- or Pharmacia, or a little bit more than 99,000; is that</p> <p>20 right?</p> <p>21 A. That's correct.</p> <p>22 Q. And that's in addition to 65 -- somewhat more than \$6,500 in</p> <p>23 expenses, right?</p> <p>24 A. That's correct.</p> <p>25 Q. And since 2001 you've received no money from Searle,</p>	<p style="text-align: right;">19</p> <p>1 the nonsteroidal anti-inflammatory drugs interfered with the</p> <p>2 production of a class of hormones called prostaglandins in</p> <p>3 the wall of the stomach and duodenum. And Andre Robert was</p> <p>4 one of the first scientists to show that the protection of</p> <p>5 the gastrointestinal tract against the formation of ulcers is</p> <p>6 remediated by prostaglandins and the way it does that is by</p> <p>7 increasing mucosal blood flow which allows the stomach to get</p> <p>8 rid of the acid, absorb the acid, by producing mucus which</p> <p>9 protected the stomach wall and the duodenal wall, and a</p> <p>10 couple of other mechanisms.</p> <p>11 So the question was, if you added this prostaglandin, I</p> <p>12 believe it's prostaglandin E2 drug, misoprostol, to</p> <p>13 nonsteroidal anti-inflammatory drugs, if you could change the</p> <p>14 incidence of complications. And this addresses an important</p> <p>15 part of this whole topic which is how do you study this type</p> <p>16 of complication. It's easy enough to say that you should do</p> <p>17 this in 8800 patients which is what this study was done in,</p> <p>18 but that's a very, very expensive study. And so you can</p> <p>19 imagine, I mean I have no idea what it costs, but it probably</p> <p>20 costs \$20 million to run a study like this. So there were</p> <p>21 considerations, including at the FDA, which I attended, on</p> <p>22 how to design a study, what kind of surrogate markers you</p> <p>23 could use.</p> <p>24 In other words, if you said, Well, if you're going to</p> <p>25 get an ulcer, then you could get an ulcer complication. So</p>
<p style="text-align: right;">18</p> <p>1 Pharmacia or Pfizer?</p> <p>2 A. That's correct.</p> <p>3 Q. Okay.</p> <p>4 MR. MONTGOMERY: At this point I'd like</p> <p>5 to ask the court reporter to mark what will be <u>Exhibit 199</u> --</p> <p>6 I'm sorry; <u>Exhibit 196</u>.</p> <p>7 (Exhibit No. 196 marked</p> <p>8 for identification.)</p> <p>9 Q. (BY MR. MONTGOMERY) Is <u>Exhibit 196</u> an article that you</p> <p>10 co-authored that was published in the Annals of Internal</p> <p>11 Medicine on August 15th, 1995?</p> <p>12 A. It is.</p> <p>13 Q. And what does this article describe, generally speaking?</p> <p>14 A. This is, to my knowledge, the first large clinical trial</p> <p>15 which examined the question of the ability to change the</p> <p>16 incidence of upper gastrointestinal complications in patients</p> <p>17 with arthritis, in this case rheumatoid arthritis, taking</p> <p>18 nonsteroidal anti-inflammatory drugs.</p> <p>19 What had happened was between about the years 1985 and</p> <p>20 1990, in that range, there became an increasing appreciation</p> <p>21 that ulcers and ulcer complications in patients were related</p> <p>22 to these drugs called nonsteroidal anti-inflammatory drugs of</p> <p>23 which there are approximately 20 to 25 different drugs, and</p> <p>24 it had been found out through work of a person named Andre</p> <p>25 Robert who at the time worked for Searle, that it seemed like</p>	<p style="text-align: right;">20</p> <p>1 if you don't have an ulcer, you're not going to get a</p> <p>2 complication, so maybe instead of studying complications you</p> <p>3 can study ulcers. And the reason that's important is that in</p> <p>4 people on nonsteroidal anti-inflammatory drugs they have</p> <p>5 about a 20 percent incidence of ulcers, so 100 people, 20 of</p> <p>6 them is going to get an ulcer, but only one of them is going</p> <p>7 to get an ulcer complication. So if it's 20 out of 100 you</p> <p>8 could improve on that if you got it down to let's say 10 out</p> <p>9 of 100 or five out of 100 with a study in 200 people. But if</p> <p>10 you want to look at the actual complication which is a</p> <p>11 one percent incidence and you want to improve on that, it has</p> <p>12 to be a very large trial.</p> <p>13 And that's why this trial was 8800 patients, it was</p> <p>14 almost 9,000 patients. And it -- I believe the FDA wanted</p> <p>15 Searle at the time to do sort of this ultimate trial. They</p> <p>16 did not want a surrogate like just an ulcer or even before an</p> <p>17 ulcer, an erosion. They wanted the actual proof about a</p> <p>18 complicated ulcer with bleeding obstruction, perforation.</p> <p>19 And so this trial was undertaken in a large group of</p> <p>20 people by a large group of physicians, 660 physicians, 8800</p> <p>21 patients, and the design of the trial was to take 10 --</p> <p>22 (Interruption.)</p> <p>23 THE WITNESS: It was to take 8800</p> <p>24 patients and -- with rheumatoid arthritis, which is one type</p> <p>25 of arthritis, but these people have very bad arthritis and</p>



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<p style="text-align: right;">21</p> <p>1 need these drugs to maintain function. But we're taking one</p> <p>2 of 10 NSAIDs, so this was a scala of NSAIDs, and then they</p> <p>3 were randomized to either taking misoprostol with the NSAID</p> <p>4 or no misoprostol with the NSAID. And then we examined the</p> <p>5 incidence of the complications. And what was shown in this</p> <p>6 study was that the complications occurred in approximately</p> <p>7 one percent of patients, which is what we knew. In fact, the</p> <p>8 FDA in all of the nonsteroidal drugs in the warning section</p> <p>9 reports that there's a one to two percent incidence -- well,</p> <p>10 that the incidence of a GI complication and/or a symptomatic</p> <p>11 ulcer is three to four percent or two to four percent, and</p> <p>12 the incidence of a complication is approximately one percent.</p> <p>13 And that's in fact what we found in this paper, that in the</p> <p>14 people who were randomized to placebo with the NSAID there</p> <p>15 was about a one percent incidence of complication. I think</p> <p>16 it was .9 percent. And with the Misoprostol, it reduced that</p> <p>17 to about .5 percent, a 40 percent reduction which was</p> <p>18 statistically significant at a P value of .049, just</p> <p>19 below .05 which was the cut off for significance.</p> <p>20 So in fact, to my knowledge, this was the first large</p> <p>21 randomized prospective trial, not a metaanalysis or, you</p> <p>22 know, a compilation of other studies, that actually directly</p> <p>23 examined patients with arthritis taking nonsteroidal drugs</p> <p>24 and whether you could reduce the incidence of these serious,</p> <p>25 potentially life-threatening complications by adding a</p>	<p style="text-align: right;">23</p> <p>1 A. Yes.</p> <p>2 Q. I'm just going to read it into the record. It says, "Design</p> <p>3 six-month randomized double blind placebo controlled trial."</p> <p>4 Do you see that?</p> <p>5 A. I do.</p> <p>6 Q. Is that an accurate description?</p> <p>7 A. It is.</p> <p>8 Q. And I'm sorry; going back a step. This whole study that</p> <p>9 <u>Exhibit 196</u> discusses, is that also referred to as the mucosa</p> <p>10 study?</p> <p>11 A. It is.</p> <p>12 Q. Okay. Is the language that I just read into the record an</p> <p>13 accurate description of the mucosa trial?</p> <p>14 A. It is.</p> <p>15 Q. What does it mean to say it's a six-month trial in that</p> <p>16 description?</p> <p>17 A. The patients were on the trial for six months unless they</p> <p>18 were taken off the trial for an adverse event, I believe, or</p> <p>19 of course for noncompliance or some other thing happening to</p> <p>20 the patient. That's why not all the patients who were -- I'm</p> <p>21 trying to remember how many patients actually made it through</p> <p>22 this trial, but it wasn't the full 8800 for a variety of</p> <p>23 reasons.</p> <p>24 Q. So unless a patient withdrew they were given either an NSAID</p> <p>25 plus placebo or an NSAID plus Misoprostol for six months; is</p>
<p style="text-align: right;">22</p> <p>1 prostaglandin to their nonsteroidal drugs, and it was</p> <p>2 positive.</p> <p>3 Q. So what is Misoprostol?</p> <p>4 A. So Misoprostol is a prostaglandin E1 analog. That's a type</p> <p>5 of prostaglandin. There are approximately 25 different</p> <p>6 prostaglandins in the bodies and they affect all the organs</p> <p>7 in the body. Misoprostol is one of these prostaglandins, and</p> <p>8 it's known to affect the upper gastrointestinal tract with,</p> <p>9 as I said, increased mucous production, increased blood flow</p> <p>10 to the lining of the stomach, and to be associated with</p> <p>11 increased resistance of the stomach wall to ulceration caused</p> <p>12 by nonsteroidal agents presumably through the COX-1</p> <p>13 mechanism.</p> <p>14 Q. (BY MR. MONTGOMERY) So would it be fair, simply put, that</p> <p>15 Misoprostol counteracts some of the negative effects in the</p> <p>16 GI tract of the NSAIDs?</p> <p>17 A. Yes, in the upper GI tract. We didn't actually study the</p> <p>18 effects which have come up recently as interesting, the</p> <p>19 effects of these drugs on the small bowel and colon which</p> <p>20 also have effects, but this was really looking at the upper</p> <p>21 GI tract.</p> <p>22 Q. Okay. I'd like you to take a look on the first page on</p> <p>23 <u>Exhibit 196</u>.</p> <p>24 A. Right.</p> <p>25 Q. The second bullet says Design; do you see that?</p>	<p style="text-align: right;">24</p> <p>1 that right?</p> <p>2 A. That's correct.</p> <p>3 Q. And then after six months they weren't given either drug</p> <p>4 anymore; is that right?</p> <p>5 A. That's correct.</p> <p>6 Q. Was there follow up after six months?</p> <p>7 A. I don't remember. If you'll give me one moment to...</p> <p>8 Q. Sure.</p> <p>9 A. I don't believe so. I mean patients of course were followed</p> <p>10 because you're concerned about a patient who might have a</p> <p>11 complication right at the end of the study, but the study</p> <p>12 lasted six months.</p> <p>13 Q. And did patients enroll in the study on a rolling basis?</p> <p>14 A. I don't understand the question.</p> <p>15 Q. Sure. Maybe I'll ask the reverse.</p> <p>16 Did every single patient in the study start taking the</p> <p>17 drug on the same day?</p> <p>18 A. No, that would be impossible. These were in a whole bunch of</p> <p>19 family practice -- family practices in North America, so the</p> <p>20 United States and Canada; to be specific, 664 practices. And</p> <p>21 you need that volume of practice so that each practice can</p> <p>22 enroll approximately 12 patients so that you have -- well, 14</p> <p>23 patients so you will have approximately 9,000 patients at the</p> <p>24 end of it. So it required that if each practice was</p> <p>25 enrolling 14 patients, they would wait until a patient with</p>



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<p>25</p> <p>1 rheumatoid arthritis came in who met the entry criteria and</p> <p>2 they would enroll -- and if that patient agreed to it with</p> <p>3 informed consent they would then enroll that patient in the</p> <p>4 study.</p> <p>5 Q. So even though it's described here as a six-month trial, the</p> <p>6 actual conduct of the trial presumably took somewhat longer</p> <p>7 than six months?</p> <p>8 A. That's correct. I believe it took two years.</p> <p>9 Q. All right. Going back to Exhibit 196, the same -- on the</p> <p>10 first page, do you see the bullet point in the first column</p> <p>11 that says Results?</p> <p>12 A. Yes, I do.</p> <p>13 Q. And does that bullet describe in summary the results of the</p> <p>14 study?</p> <p>15 A. It does.</p> <p>16 Q. Were those results for the full six months of the study?</p> <p>17 A. Yes.</p> <p>18 Q. Do you know, in this paper, Exhibit 196, did you ever analyze</p> <p>19 any time period other than six months of data?</p> <p>20 A. Not that I recall.</p> <p>21 Q. Outside of the paper, when you got the results of the study,</p> <p>22 did you ever analyze the results for any time period other</p> <p>23 than six months?</p> <p>24 A. Not that I recall.</p> <p>25 Q. Why not?</p>	<p>27</p> <p>1 little bit more specific about the "little or no warning,"</p> <p>2 because in fact I think that -- I think that patients who</p> <p>3 develop NSAID induced ulcers are likely to have antecedent</p> <p>4 symptoms. So I think "little or no warning" is a little bit</p> <p>5 vague. In other words, if I have an ulcer and if I'm</p> <p>6 symptomatic, I have -- you're my physician and I go in to see</p> <p>7 you and I say, I'm taking the drug you gave me but I'm not</p> <p>8 feeling well, I have pain here (indicating), that would be a</p> <p>9 symptom, you might endoscope me and see an ulcer.</p> <p>10 The fact that I was about to develop a massive</p> <p>11 hemorrhage or a perforation might not give you -- it might</p> <p>12 not be warning of that until the event occurred. So I think</p> <p>13 that from my knowledge most patients who develop an upper GI</p> <p>14 ulcer complication are in fact symptomatic, not all of them,</p> <p>15 but somewhere between 50 and 95 percent from the literature</p> <p>16 of patients who develop a complicated ulcer are in fact</p> <p>17 symptomatic, but going from the complicated ulcer to the</p> <p>18 perforation or hemorrhage may occur without any other warning</p> <p>19 that it's going to happen other than the event occurring</p> <p>20 itself.</p> <p>21 And I did -- as part of this question about who's</p> <p>22 bleeding, I just want to give you a touch of background. I</p> <p>23 spent eight years, so 1973 to 1981, looking at the question</p> <p>24 as to whether an endoscopist who's looking into somebody's</p> <p>25 stomach and who sees an ulcer and who sees bleeding from the</p>
<p>26</p> <p>1 A. The study was designed to be a six-month study. We got data</p> <p>2 in patients over a six-month period for each patient and</p> <p>3 that's what we analyzed.</p> <p>4 Q. So before you performed the mucosa study, did you have a plan</p> <p>5 for how you were going to analyze the results once you got</p> <p>6 them?</p> <p>7 A. Yes.</p> <p>8 Q. And did that include analyzing the results for six months?</p> <p>9 A. Yes.</p> <p>10 Q. And you followed that plan once you got the results?</p> <p>11 A. Yes.</p> <p>12 Q. All right. Still on the first page of Exhibit 196, on the</p> <p>13 right-hand column, the second paragraph that starts General</p> <p>14 Physicians; do you see that?</p> <p>15 A. I do.</p> <p>16 Q. I'd like you to take a look at the last sentence in that</p> <p>17 paragraph. I'm going to read it into the record. It says,</p> <p>18 "Life-threatening events such as perforations or serious</p> <p>19 hemorrhage from NSAID induced ulcers which also develop with</p> <p>20 little or no warning are a real problem because of the many</p> <p>21 patients at risk."</p> <p>22 Do you see that?</p> <p>23 A. I do.</p> <p>24 Q. And was that true at the time this article was published?</p> <p>25 A. I would say that were I to write it again, I might be a</p>	<p>28</p> <p>1 ulcer can treat that ulcer right then and there and stop the</p> <p>2 bleeding. I did it in association with an engineer who's now</p> <p>3 fairly famous named David Off and he and I ran an NIH funded</p> <p>4 group that examined various methods of stopping the bleeding,</p> <p>5 and that included lasers and heat and cooling and even</p> <p>6 cyanoacrylate glue and electrocautery, et cetera. We</p> <p>7 developed models of bleeding, so this is hands-on, first</p> <p>8 person experience in upper gastrointestinal bleeding. We</p> <p>9 developed models -- because the people before that were using</p> <p>10 different models and different therapies. They didn't even</p> <p>11 know how much therapy was being applied and so we tried to</p> <p>12 get control over that by, No. 1, understanding the treatment</p> <p>13 method, and No. 2, understanding the bleeding model.</p> <p>14 And we in fact did invent, if you will, two devices</p> <p>15 which are still used today in patients with bleeding to</p> <p>16 control the bleeding. But in my reading at the end of that</p> <p>17 period of time, so this is 10 years of my life almost, at the</p> <p>18 reading of the end of that time and we wrote 35 papers or so,</p> <p>19 peer-reviewed papers about the different things we studied,</p> <p>20 it became clear to me that we had this problem of who was</p> <p>21 bleeding and who was at risk. And it goes back to what I</p> <p>22 said awhile ago about this issue about surrogate markers, you</p> <p>23 know, how do you know? I mean if you want to study</p> <p>24 mortality -- now, we talked about 100 patients, 20 of them</p> <p>25 will get an ulcer. One percent will have a complication.</p>



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<p style="text-align: right;">29</p> <p>1 But if you have an ulcer complication, one in 10 of those  2 people will die. But if you look at the numbers then, it's a  3 thousand patients take the drug, 200 get an ulcer, that's  4 20 percent, 10 get a complication, that's one percent, and  5 one will die.  6 So if you think it's difficult to design a trial that  7 looks at a complication, it's that much more difficult to  8 design a trial that looks at mortality, which is really in  9 some ways one of the most important -- one of the most  10 important things to look at.  11 So in the study -- I did another study then in which I  12 worked with the American Society for Gastrointestinal  13 Endoscopy which resulted in four papers, which are in my  14 curriculum vitae, in 1982, in which we looked at 2200  15 patients from 250 doctors and we looked at them prospectively  16 so that means that we did go back and say, Hey, in your  17 practice in the last five how many bleeders have you seen?  18 We didn't do it that way. We rather asked each physician  19 participating to give us a prospective entry of a patient  20 with upper gastrointestinal bleeding, and we produced what I  21 would say was an unbelievable amount of data.  22 We had six full pages of data on 2200 patients and  23 every one was carefully examined. And I had a wonderful,  24 very compulsive assistant who sent back about 95 percent of  25 the forms to doctors to get it more completely filled out.</p>	<p style="text-align: right;">31</p> <p>1 So I know I digressed a bit but I think it's important  2 to establish my feeling about the fact that if you give  3 people NSAIDs a lot of them get symptoms. 40 percent of  4 people on these drugs get symptoms. But only a very small  5 number of those go on and get a complication. And if you  6 look at the complications and look back the other way, then I  7 think that in fact most or a significant portion of people  8 with complications have had symptoms, and therefore if you  9 were to eliminate patients with symptoms you would be  10 eliminating a lot of the patients who go on to develop  11 complications.  12 So I would just say in retrospect now when looking at  13 that sentence you asked me about, I think "with little or no  14 warning" means that you may have stomach upset and I may be  15 treating you with antacids or histamine two receptive blocker  16 while you're talking the drug, the nonsteroidal drug, but the  17 person who's going to come in and suddenly develop a  18 perforation or vomit blood, we don't know that until it  19 occurs, and I think that's what that sentence meant.  20 Q. Okay. So approximately how many people that go on to  21 experience ulcer complications have GI symptoms first?  22 A. That's a good question and I don't know the exact answer but  23 I would say it was somewhere between 50 and 90 percent from  24 the literature and from my own study where we looked at it  25 and found that people with gastric ulcer and duodenal ulcer</p>
<p style="text-align: right;">30</p> <p>1 So in that study, it produced a huge amount of data. I  2 sometimes refer to it as almost a soapstone, piece of stone  3 data, and the question was what carvings would you make from  4 that? What would you examine?  5 And in that data the patients with bleeding,  6 approximately 25 percent were from a duodenal ulcer,  7 25 percent were from a gastric ulcer. 20 percent were from  8 erosive disease, which is sort of an early ulcer, it's very  9 shallow, and the other 30 percent were other lesions like  10 esophageal varices which are dilated veins, or  11 Osler-Weber-Rendu which are little bleeding spots, little  12 bleeding spots in the stomach.  13 And also in that study 50 percent of the patients had  14 antecedent symptoms. So if you just say that 50 percent of  15 patients in this study had antecedent symptoms, I believe --  16 although I did not study this at the time, I didn't ask the  17 technician and the statisticians to look at this -- that of  18 half of the patients who bled from ulcers, either the stomach  19 or duodenum, that these were in fact symptomatic patients.  20 At least 50 percent of them were symptomatic.  21 And then there are articles by other people like  22 Michael Langman and several other authors, Peter Cotton I  23 believe, looking at the same question, showing 70 or  24 90 percent of patients presenting with an upper GI bleed as  25 being symptomatic.</p>	<p style="text-align: right;">32</p> <p>1 were 50 percent of patients, and 50 percent of patients had  2 symptoms. And the other diagnoses often don't have symptoms.  3 For example, esophageal varices, dilated veins in the  4 esophagus, do not present with symptoms of an ulcer. So I  5 think that most of the patients with ulcers had symptoms but  6 I can't give you that exact number.  7 Q. Somewhere between 50 and 90 percent?  8 A. That's correct.  9 Q. Okay. And did you have that information at the time you  10 wrote Exhibit 196 in 1995?  11 A. Well, yes, I did. Some of it. I had -- certainly I had my  12 own studies which were done 10 years before that. So I had a  13 large portion of this information, yes.  14 Q. All right. And at this time -- well, let me ask it a  15 different way.  16 Are patients who suffer GI symptoms more likely to  17 later on develop ulcer complications?  18 A. You know, that's a fair question but it's not precise enough.  19 More likely than what?  20 Q. Oh, okay. More likely -- let me ask it again then.  21 Are patients who are taking these NSAIDs who experience  22 GI symptoms more likely to develop ulcer complications than  23 the same sorts of patients who don't experience GI symptoms?  24 A. I would say that's probably true, yes.  25 Q. Okay. And why do you say that?</p>



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<p style="text-align: right;">33</p> <p>1 A. Well, because -- I want to go back again to this question 2 about the surrogate marker. So in other words, if we were 3 together and we were designing a trial now, somebody might 4 say, Well, let's do this trial with the fewest patients we 5 can. I mean that's a given. Because you don't want to put 6 patients through a trial if you don't have to. From an 7 ethical standpoint you want to do a study with as few 8 patients as you can. So somebody might say, Well, you know, 9 death. Well, death, you're going to have to study 90,000 10 patients. A complication, 8,000 patients. So death is a 11 tenth of a percent. A complication is one percent. A 12 complication and symptomatic ulcers is four percent. 13 Symptoms of 50 percent, 40 percent. 14 So I think if you take 100 people on nonsteroidal 15 agents, about 50 percent of them, 40 percent of them get 16 symptoms. But I don't think having symptoms predicts that 17 you're going to have a complication. I think it's too large 18 a group. It's an order of magnitude more people than are the 19 people that actually develop these things. So I think what 20 we're saying is -- what I'm saying is, if you have 100 people 21 and 50 of them are going to get symptoms and 50 don't, you 22 can't tell. You can't use symptoms as a surrogate marker, 23 you've got to go further down the chain. You've got to 24 either find an ulcer at endoscopy, have symptomatic ulcer or 25 actually have a complication or have mortality.</p>	<p style="text-align: right;">35</p> <p>1 A. I don't think I can quantify that because if you have 100 2 people and 50 get symptoms and 50 don't, of the people that 3 get the symptoms it's still only one percent that get a 4 complication. So it's very hard -- you know, I don't know. 5 It's a fair question but I don't know the answer to that. I 6 don't know that anybody has ever -- I know that other papers 7 that I have reviewed, and I don't know if they're in the -- 8 in the literature or in this paper, but reported that up to 9 90 percent of people with ulcers had symptoms but it -- it 10 tells you that, it doesn't tell you the reverse. It doesn't 11 tell you if you have symptoms versus not have symptoms the 12 likelihood of getting an ulcer or an ulcer complication. 13 And I think part of the problem, part of the problem 14 with this whole field is you're looking at orders of 15 magnitude of numbers and that's why you have to use so many 16 patients. I mean nobody in their right mind would do a study 17 in 9,000 patients if you didn't have to. The reason we did 18 these studies, the mucosa study, the CLASS study, the CONDOR 19 study, the Vioxx study, was in order to improve on one 20 percent you have to have a lot of patients. So I'm sorry; I 21 don't think I can answer it coming in symptoms versus no 22 symptoms but I can answer it on the other side that most of 23 the people with complications have had symptoms. 24 Q. Okay. Let's go back to the time period 1995 when you wrote 25 this paper. At that point did you believe that people --</p>
<p style="text-align: right;">34</p> <p>1 So we have to go back to your question again. Does the 2 presence of symptoms increase an increased likelihood of 3 having a complication? I think the answer is yes, but it's 4 still not very indicative because so many people get symptoms 5 who don't develop a complication and nobody knows why -- to 6 my knowledge, nobody knows why these people get symptoms. It 7 may be because of damage. It may be a cerebral effect. Some 8 of these drugs may have what's called a central effect, 9 producing nausea or pain. It may be an effect on motility 10 which means the way your intestine contracts, that may give 11 you some symptoms, and it may be damage further down the GI 12 tract. Which is I think an important factor with 13 nonsteroidal incidence is injury to the stomach and duodenum 14 but equally injury to the small bowel and colon. 15 So symptoms by themselves I don't think are terribly 16 helpful. 17 Q. Okay. 18 A. Does that make sense? 19 Q. Yes. I'm just going to have to follow up a little bit. 20 So just to clarify, you believe that GI symptoms are -- 21 I'm sorry. Patients taking NSAIDs that suffer GI symptoms 22 are somewhat more likely to develop ulcer complications than 23 patients that don't? 24 A. I believe that, yes. 25 Q. Okay. How much more likely?</p>	<p style="text-align: right;">36</p> <p>1 patients taking NSAIDs who suffered GI symptoms were more 2 likely to suffer GI complications than patients who didn't 3 suffer symptoms? 4 A. It's 15 years ago but I believe I would answer that yes. 5 Q. Okay. Now, we're talking about the mucosa trial right now. 6 In that trial did some patients withdraw because of GI 7 symptoms? 8 A. I don't remember. I'd have to go back and look at the -- at 9 what happened. I'm sure -- 10 Q. All right. Let's take a look at Page 245 of <u>Exhibit 196</u>. 11 A. Yeah, okay. 12 Q. Do you want to take a look at it for a sec? 13 A. Right. 14 Q. Let me know when you're -- you've had a chance to review it. 15 A. Specifically -- what specifically? 16 Q. Table 2. I'm sorry. 17 A. Table 2, okay. (Witness complies.) Okay. 18 Q. All right. Does Table 2 set forth the reasons for premature 19 withdrawal from the mucosa study? 20 A. Yes. 21 Q. All right. And does it indicate that some of the patients 22 that withdrew from the study did so because of GI symptoms? 23 A. It does. 24 Q. And which of these adverse events would you characterize as 25 GI symptoms?</p>



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<p style="text-align: right;">37</p> <p>1 A. Well, under the category of Adverse Events they are all GI 2 symptoms. 3 Q. Okay. And -- I'm sorry. In Table 2 of Exhibit 196 there's a 4 column for the Misoprostol group; do you see that? 5 A. Yes. 6 Q. And is that patients that were taking NSAIDs plus 7 Misoprostol? 8 A. Yes. 9 Q. All right. And the other column says Placebo Group. Is that 10 patients who were taking NSAIDs and a placebo? 11 A. Yes. 12 Q. Okay. Now, just looking at -- comparing the reasons for 13 withdrawal of the Misoprostol group from the placebo group, 14 does it appear that more patients withdrew because of GI 15 symptoms from the Misoprostol group than from the placebo 16 group? 17 A. It does. 18 Q. Okay. If patients who suffer GI symptoms are more likely to 19 go on to suffer ulcer complications, wouldn't the 20 differential withdrawal set forth in Table 2 bias the results 21 of the study? 22 A. Well, before I answer that I want to make an observation. 23 Misoprostol causes some of these events. Misoprostol is 24 known to cause stomach upset. That's one of the drawbacks to 25 my knowledge of the drug, it is not as well tolerated as</p>	<p style="text-align: right;">39</p> <p>1 effects. Which did cause the patient to come off the trial. 2 I mean you would say, Yeah, well, these patients did come off 3 the trial, but they came off because of side effects of the 4 Misoprostol in my opinion, not because they were 5 developing -- for example, the abdominal pain which also can 6 be Misoprostol, there was much less of a difference than in 7 something like the diarrhea which there was a huge 8 difference. You know, there was more than a two-fold, almost 9 a three-fold increase in the Misoprostol group, whereas in 10 the abdominal pain there was just a 30 percent increase. 11 And dyspepsia, which means a sour stomach, you know, 12 sort of -- dyspepsia means a burning sensation here -- and 13 that's one of the typical symptoms of an ulcer also can be 14 from Misoprostol but if you look at that you'll see that it 15 went from 180 to 200. And I think that the big difference in 16 these groups were in the GI side effects that are directly 17 attributable to the Misoprostol on GI motility. 18 Q. Is there any way -- well, let me ask it a different way: 19 Some of the people that withdrew for GI events in the 20 Misoprostol group -- strike that question. 21 Is there any way to determine which of the people in 22 the Misoprostol group withdrew because of adverse GI events 23 caused by the Misoprostol as opposed to caused by the NSAID? 24 A. That's a very fair question and I don't think there is. It's 25 a logical question because from what I'm saying you have side</p>
<p style="text-align: right;">38</p> <p>1 other drugs. So I think some of these are a direct effect of 2 the Misoprostol and not necessarily a symptom caused by early 3 development of an ulcer in the stomach or duodenum. 4 Q. It's -- I'm sorry. Go ahead. 5 A. So it's difficult to separate those. I would have to -- you 6 know, for example, diarrhea, which was a large component of 7 the patients who withdrew and -- much more diarrhea occurred 8 in the Misoprostol group than in the placebo group, that is 9 to my knowledge an effect directly of the Misoprostol, a side 10 effect of the Misoprostol, having nothing to do with damage 11 to the stomach or duodenum that would present as ulcer 12 symptom. 13 Diarrhea -- you asked if it was a GI symptom and the 14 answer is yes. If you want to know if it's an ulcer symptom, 15 the answer is no. It's not an ulcer symptom. It's a symptom 16 of increased motility of the colon producing liquid stools. 17 So that makes this a little bit more difficult in the 18 sense -- and nausea or flatulence, passing excessive gas, 19 which again was more positive in the Misoprostol group, is 20 not a sign of ulcer disease, it's a sign of the same 21 increased motility in the colon and that's a direct effect of 22 the Misoprostol. 23 So I think that these adverse events are different than 24 the adverse events that would be noted in a straight NSAID 25 trial because the Misoprostol produces these motility side</p>	<p style="text-align: right;">40</p> <p>1 effects from Misoprostol which have nothing to do with the 2 NSAID and then -- and so, for example, in a trial like the 3 PPI trial, PPI is a proton pump inhibitor, they pretty well 4 tolerate it. They don't have many sides effects. So there 5 you can say, Well, you know, you can't say it was due -- to 6 my knowledge. I mean when the PPIs first came out we all 7 worried with them because they shut off gastric acid so 8 profoundly. Or an H2 blocker like cimetidine. They don't 9 have much in the way of side effects. 10 So whether you're taking an H2 blocker or not, I don't 11 think you can tell unless you had something like heartburn 12 which got better. But that's not true of Misoprostol. 13 Misoprostol does have more systemic effects than the two 14 agents that are used to control gastric acid, the two classes 15 of agents, H2 blockers and proton pump inhibitors. 16 So although your question is a good question, I don't 17 think there's any way to do that from this, and at the time 18 it didn't seem -- that question didn't occur to us. It's 19 always different when you look at these studies in retrospect 20 than when we're actually up to elbows in the data 21 prospectively. 22 Q. Okay. So going back to Table 2, Exhibit 196, just to 23 confirm, more people withdrew from the Misoprostol group 24 because of GI symptoms, correct? 25 A. That is correct.</p>



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September 29, 2010

<p style="text-align: right;">41</p> <p>1 Q. At the time that you got these results for the mucosa trial, 2 did that cause you any concern then that the results of the 3 study might have been biased by that differential withdrawal? 4 A. You know, it didn't, and I think the reason it didn't was the 5 nature of the reasons for the withdrawal. In other words, 6 diarrhea, it's like I know they're going to get diarrhea. 7 First of all, patients get diarrhea, that's in the placebo 8 group, but the fact that there was so much more diarrhea in 9 the Misoprostol group is more attributable -- these 10 prostaglandin have effects throughout the body. They affect 11 every body tissue. And they do produce these effects like 12 the motility of the colon. 13 So I don't remember thinking about that specifically, 14 but I would have done what I just did which is write the 15 symptoms off -- the difference in the symptoms off in large 16 part to the effect of Misoprostol on the gut and not that we 17 were taking patients out of the trial who were more 18 susceptible to developing an ulcer. 19 Q. By the way, I didn't mention it in our prologue but if you 20 ever want to take a break for any reason -- 21 A. Thank you. 22 Q. -- let me know and we'll usually follow up whatever question 23 we're on and then we can go off the record. So any time you 24 need it. 25 A. Okay. Thank you.</p>	<p style="text-align: right;">43</p> <p>1 so it's not far off. I was just reporting that other studies 2 have reported a higher -- and perhaps since then have 3 reported a higher incidence of symptoms in patients with 4 ulcers, but what you just read to me reported that 58 percent 5 did -- first presented with the complication and the 6 corollary of that is 42 percent had symptoms. 7 And the other thing I would mention is that I think 8 there are symptoms and there are symptoms, meaning that it 9 depends on how the person is asked about the symptoms. When 10 a patient comes in with an upper GI bleed, they're vomiting 11 blood, they've got bloody stools, they're in shock. The 12 history from that patient I don't think is as reproducible 13 necessarily as the history taken in this room if we were 14 sitting here and I asked you, Have you got any symptoms? So 15 I'm always a little bit suspect, I don't mean in an evil way, 16 I just -- I'm not as comfortable with the broad category of 17 symptoms prior to a big event because the big event is such a 18 catastrophic event that the patient then, you know, I don't 19 know, I don't know. Look, I'm just, you know. And it may 20 not be -- so in other words, if they reported 58 percent 21 didn't have symptoms, I think I would trend to say that would 22 be high. I think most of them did have symptoms, more than 23 42 percent. But it's not far off of what I reported from the 24 study that I did. 25 Of interest, just to -- plus I feel like saying it I</p>
<p style="text-align: right;">42</p> <p>1 MR. MONTGOMERY: I'd like to ask the 2 court reporter to mark what will be Exhibit 197. 3 (Exhibit No. 197 marked 4 for identification.) 5 Q. (BY MR. MONTGOMERY) Is Exhibit 197 an article you published 6 in Digestive Diseases and Science in March of 1998? 7 A. It is. 8 Q. Would you turn to the second page of Exhibit 197, please. 9 A. (Witness complies.) 10 Q. In the right-hand column on that page, about halfway down the 11 page I'd like to read something into the record. "58 percent 12 of patients admitted to the hospital with life-threatening 13 complications associated with NSAID ulcers, the first 14 evidence of gastrointestinal disease was the complication 15 itself." 16 Do you see that? 17 A. Yes. 18 Q. How is that consistent with what you were saying before that 19 50 to 90 percent of people are symptomatic before suffering a 20 GI complication? 21 A. Right. Well, if you look at the flip side of what you just 22 said, 42 percent of patients admitted to the hospital with a 23 threat did have some other warning. And remember, I said 24 that in my study that I did of the 2200 patients for the 25 ASGE, the national society, it was 50 percent or 47 percent,</p>	<p style="text-align: right;">44</p> <p>1 guess, this paper goes on and talks about the fact that 2 Helicobacter pylori has now emerged as -- at this point. You 3 know, we're working on the chronology of understanding what's 4 happening, this is 1998. I think it was 1995 when there was 5 an NIH consensus conference chaired by Dr. Yamada which 6 addressed the question of what causes ulcers. And when I 7 went to medical school at Columbia in 1963 we were taught it 8 was stress, and some people still think that unbelievably. 9 What has emerged is that there are two causes of ulcers, 10 nonsteroidal anti-inflammatory disease and Helicobacter 11 pylori. 12 MR. WEISS: You might want to slow down 13 and say the name of that bug again for the court reporter. 14 THE WITNESS: Excuse me. H pylori. H, 15 P-Y-L-O-R-I. 16 So by the time I wrote this I was saying that about 17 half of all ulcers are caused by NSAIDs, and mind you, I 18 think there were 90 drugs I found that had aspirin in it, 19 many of which the patients didn't know contained aspirin like 20 222s and Excedrin Plus, I mean all these different types of 21 drugs that had aspirin. That accounts for about 50 percent 22 of ulcers, and Helicobacter pylori accounts for 50 percent of 23 ulcers. 24 So in the evolution of our knowledge of ulcer disease, 25 by this point, by '98 we had learned that half of the ulcers</p>



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<p style="text-align: right;">45</p> <p>1 were H pylori which is a bug you can pick up and which is</p> <p>2 treatable with antibiotics, it was a huge advance in our</p> <p>3 knowledge of ulcer disease. And the guy who figured it out</p> <p>4 was an Australian fellow named Barry Marshall who took H</p> <p>5 pylori himself, nobody would believe him so he swallowed it</p> <p>6 himself and he got sick. And he then demonstrated that it</p> <p>7 was a direct effect. He didn't get an ulcer but aside from</p> <p>8 that everything was perfect. He got really sick. And he won</p> <p>9 the Nobel prize for that, so this was a serious</p> <p>10 accomplishment.</p> <p>11 So he single-handedly, against all the establishment of</p> <p>12 gastroenterology, showed that H pylori was a significant</p> <p>13 agent. And in 1995 the consensus conference at the NIH,</p> <p>14 which was three days, hundreds of people were there, 18 of us</p> <p>15 were on the panel, considered whether H pylori was a major</p> <p>16 cause of ulcer disease and concluded that it was and really</p> <p>17 changed the approach to ulcer disease from a pathophysiology</p> <p>18 standpoint in that we now knew that a lot of ulcers of course</p> <p>19 were H pylori which were treatable with antibiotics, which</p> <p>20 was fabulous. So now we were left with the other half which</p> <p>21 were NSAIDs, so it continued the focus on NSAIDs and how</p> <p>22 could you make NSAIDs less injurious.</p> <p>23 Q. So did Dr. Marshall win the Nobel prize for medicine or</p> <p>24 bravery?</p> <p>25 A. Yes. He won it actually for medicine and he started an</p>	<p style="text-align: right;">47</p> <p>1 produce erosions, ulcerations, eventually ulcer</p> <p>2 complications. So the hypothesis that was being developed</p> <p>3 at, I believe it was Barnes University where Dr. Needleman</p> <p>4 was working and I guess there were other people working in</p> <p>5 the field as well, was that there were two classes of drugs</p> <p>6 regarding their effect on the Cox enzymes, drugs that</p> <p>7 affected both and drugs that just affected COX-2. And so the</p> <p>8 hypothesis was, if you only affected COX-2 to decrease the</p> <p>9 inflammation by decreasing that enzyme, but you didn't change</p> <p>10 to COX-1 which was the protective mechanism, that you might</p> <p>11 then have less of an injurious effect on the upper GI tract.</p> <p>12 So that was the -- sort of the overall hypothesis going</p> <p>13 into the trial.</p> <p>14 (David Goldberger enters.)</p> <p>15 THE WITNESS: Now, what comes up again</p> <p>16 now is how do you prove that? Which is what I've been</p> <p>17 talking about as a recurring theme this morning is this issue</p> <p>18 about how do you model that. Now, ultimately you would say,</p> <p>19 Let's look at mortality. I mean, you know, My mother is</p> <p>20 going on the drug, I want to know if she's at risk for dying.</p> <p>21 Well, I've told you to do that, you're probably at 90,000</p> <p>22 patients, because it's a piece of a piece of a piece of this.</p> <p>23 So then you could back up and say, Okay, we can't really do</p> <p>24 mortality, unless you use the study I did in the '80s and</p> <p>25 said, Hey, the real mortality is in people with liver disease</p>
<p style="text-align: right;">46</p> <p>1 institute. He's got his own institute and it was -- it was</p> <p>2 an interesting thing that he did that.</p> <p>3 Q. So were you involved in the design of the CLASS study?</p> <p>4 A. You know, I was not. To my recollection I was not involved</p> <p>5 in the design of the CLASS trial. It was designed before I</p> <p>6 was asked to participate. Again, that was 14 years ago</p> <p>7 and -- but to the best of my knowledge early on I was not</p> <p>8 involved.</p> <p>9 Q. All right. Do you know what the purpose of the CLASS study</p> <p>10 was?</p> <p>11 A. I do.</p> <p>12 Q. And what was that?</p> <p>13 A. So the purpose of the CLASS trial was to examine the</p> <p>14 hypothesis that if you took a drug which was a mostly</p> <p>15 selective COX-2 inhibitor that had antiarthritic effects,</p> <p>16 that you would produce less injury to the GI tract than a</p> <p>17 standard NSAID which had both COX-1 and COX-2 effects. So</p> <p>18 let's go back and explain what that means.</p> <p>19 There seemed to be two effects, deleterious or -- two</p> <p>20 effects of NSAIDs and related drugs on the GI tract. One is</p> <p>21 to decrease COX-1, and COX-1 is psycho oxygenates which</p> <p>22 produces the prostaglandins which are helpful to the stomach</p> <p>23 and duodenum. They help protect the stomach and duodenum, so</p> <p>24 you would like to allow that to continue happening. COX-2</p> <p>25 are the -- are -- produces the inflammatory chemicals that</p>	<p style="text-align: right;">48</p> <p>1 who are over 60. I mean the purpose of those studies that I</p> <p>2 did in the late '70s and early '80s was to really be able to</p> <p>3 define who was at really increased risk.</p> <p>4 But the more you start to narrow a study, the more you</p> <p>5 start to cut in on the study, kind of less applicable it is.</p> <p>6 This will come up later in terms of other parts of the Cox --</p> <p>7 of the CLASS and other trials. In other words, if you say</p> <p>8 it's only in women, not men, and it's only age of 40 to 60,</p> <p>9 well, the more you close in on it the less applicable the</p> <p>10 data may be to other groups. So you don't want to do</p> <p>11 bleeding. You don't want to do rather death. You can back</p> <p>12 up and say, Let's do complications, and ulcer perforations is</p> <p>13 a pretty clear complication. I mean that's known.</p> <p>14 Obstruction is not quite as clear but it's pretty clear.</p> <p>15 Bleeding is complex, and we'll probably talk about that in a</p> <p>16 bit. But those are complications, bleeding, obstruction and</p> <p>17 perforation are complications. And those are one or</p> <p>18 two percent, not .1 percent death but one or two percent. So</p> <p>19 that's -- we could examine that.</p> <p>20 Symptomatic ulcers, you back up and include that,</p> <p>21 that's going to be two or four percent. You can back up from</p> <p>22 that and say ulcers, you know, endoscope, take 100 people,</p> <p>23 give them the drug, look down and see who gets an ulcer. You</p> <p>24 can back up from that and say an erosion, which is a</p> <p>25 superficial ulcer, that's not -- that doesn't go deep. It</p>



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<p style="text-align: right;">49</p> <p>1 doesn't involve the submucosal layers of the intestinal wall.</p> <p>2 I don't think symptoms help for the reasons we</p> <p>3 discussed a few minutes ago. I don't think symptoms are good</p> <p>4 because so many people have symptoms. So the other thing you</p> <p>5 could do is you could look at GI bleeding. You could look at</p> <p>6 anemia. You could look at blood in the stool called</p> <p>7 hemoccult positivity.</p> <p>8 And what had happened, I think it was 1998 when Searle</p> <p>9 went to the FDA and got celecoxib approved. This is 12 years</p> <p>10 ago so I don't exactly remember the date but I remember that</p> <p>11 I went. And I was the person who presented the GI data</p> <p>12 and -- was that -- anybody know? Was that 98 when celecoxib</p> <p>13 was first approved?</p> <p>14 Okay. When we made the argument for celecoxib, it was</p> <p>15 based on about 14 different studies, studies in which you</p> <p>16 looked down and you said, you know, Hey, you give people</p> <p>17 Naproxen, Indocin, Butazolidin, about 20 percent of them are</p> <p>18 getting ulcers, three or four percent with celecoxib. If you</p> <p>19 look at erosions, it's much more with the standard NSAIDs</p> <p>20 than celecoxib. If you look at blood in the stool, it's more</p> <p>21 with the standard NSAIDs than celecoxib. If you look at</p> <p>22 anemia, it's more with the standard NSAIDs than celecoxib.</p> <p>23 So there was a body of data which Searle presented to</p> <p>24 the FDA as part of the following statement: Celecoxib would</p> <p>25 appear to be a safe and effective drug from a rheumatic</p>	<p style="text-align: right;">51</p> <p>1 the complication.</p> <p>2 Now, I personally feel that you aren't going to develop</p> <p>3 a complicated ulcer if you haven't got an ulcer. And so if I</p> <p>4 could take a drug and say, you know, This drug has</p> <p>5 one percent incidence of ulcers and this drug has 20 percent</p> <p>6 incidence of ulcers, I'll take the one percent incidence,</p> <p>7 that's the drug I'd rather take. But the counter argument to</p> <p>8 that is, Yeah, well, maybe it's the little ulcers that aren't</p> <p>9 present. In other words, in the patients taking NSAID A,</p> <p>10 they get 20 percent of ulcers, but a lot of them are tiny</p> <p>11 little ulcers that don't mean anything. They have one</p> <p>12 percent of bad ones and this other drug is one percent of bad</p> <p>13 ones, so you haven't really improved. And that's the</p> <p>14 argument -- that's the only argument I can think of against</p> <p>15 my argument which is, This is crazy. If I'm going to give</p> <p>16 this drug to my child and one is one percent and one is</p> <p>17 20 percent ulceration, and since you got to have an</p> <p>18 ulceration before you develop a complicated ulceration --</p> <p>19 there's only one exception to that which is a fountain</p> <p>20 Dieulafoy which is a whacky GI lesion with a little blood</p> <p>21 vessel sticking up. No one knows why it happens, a little</p> <p>22 blood vessel spurting away. But those are in less than one</p> <p>23 percent of bleeders.</p> <p>24 So a fountain Dieulafoy -- we'll spell it later -- but</p> <p>25 that's a very rare lesion. Otherwise the complications are</p>
<p style="text-align: right;">50</p> <p>1 standpoint, it works on arthritis and it seems to be safe and</p> <p>2 effective, but we think it also has less injurious effects on</p> <p>3 the stomach. And they used those studies I was just talking</p> <p>4 about, fewer erosions, fewer ulcerations, fewer patients with</p> <p>5 bleeding, fewer patients a little bit of bleeding in the</p> <p>6 stool, fewer patients with anemia. And Dr. Needleman got up</p> <p>7 and he said, you know, The standard NSAID is approved with</p> <p>8 1500 to 2,000 patients. I have studied 15,000 patients.</p> <p>9 So there's a huge body of information about celecoxib</p> <p>10 and its safety. And he was asking for the indication in</p> <p>11 the -- whatever the FDA calls it, that celecoxib was less</p> <p>12 injurious to the GI tract.</p> <p>13 Now, the FDA said, no, that isn't good enough data yet.</p> <p>14 You haven't shown -- you got to go further down the chain in</p> <p>15 order to get us to do that. And the reason they said that</p> <p>16 was this is a big issue. There are so many patients taking</p> <p>17 nonsteroidal antiinflammatory drugs of all different kinds,</p> <p>18 and with the numbers that we talked about, there are a lot --</p> <p>19 hundreds of thousands of patients presenting with bleeds.</p> <p>20 And so the FDA was dealing with this question, and they're</p> <p>21 just folks like we are. I mean they're as smart as we are</p> <p>22 and we're as smart as they are and you're working on solving</p> <p>23 problems, so they were pushing for taking it further down the</p> <p>24 chain even though it was going to take 6- to 8,000 patients,</p> <p>25 and looking at the actual complication and not surrogates for</p>	<p style="text-align: right;">52</p> <p>1 all in all ulcers. You got to have an ulcer before you</p> <p>2 develop a perforation, a bleed or obstruction.</p> <p>3 So -- however, the FDA felt, No, that's not good</p> <p>4 enough. What they were basically saying was, the importance</p> <p>5 of this distinction of being able to say that the drug is</p> <p>6 really safer, from the GI bleeding complication standpoint</p> <p>7 it's so high that we want you to take it further down the</p> <p>8 chain and look at actual complications, and so that's how --</p> <p>9 that was sort of the fundamental part of how the CLASS trial</p> <p>10 was designed.</p> <p>11 Q. So when you met with the FDA in '98, at that point the drug</p> <p>12 was already approved, correct?</p> <p>13 A. Well, yes, the drug was approved. I had met with the FDA in</p> <p>14 the late '80s. We had a very energetic -- actually one of</p> <p>15 the few sessions I've ever been at where people were yelling</p> <p>16 at each other. The doctors were yelling at each other about</p> <p>17 this issues about surrogates. Some people were saying,</p> <p>18 Baloney, you got to have the ulcer, you got to have the</p> <p>19 bleed.</p> <p>20 So I went to -- the FDA didn't do that again, maybe</p> <p>21 because it was such an energized section. I mean these were</p> <p>22 the quote, leaders, unquote, in the area and everybody was</p> <p>23 yelling at each over, it was sort of funny. But we had that</p> <p>24 one day which I believe was in the late '80s, then the</p> <p>25 issue -- Misoprostol was approved -- I mean excuse me --</p>



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<p style="text-align: right;">53</p> <p>1 Celebrex was approved and then we went back to the FDA to</p> <p>2 discuss the issue about, Okay, the data that we presented at</p> <p>3 the filing didn't convince the FDA that Misoprostol was less</p> <p>4 injurious. What do you have to do to get that?</p> <p>5 Q. Did you mean Celebrex?</p> <p>6 A. Excuse me. I meant Celebrex. That the data we presented</p> <p>7 when Celebrex was approved -- all of which by the way, one of</p> <p>8 the compelling things in my mind was every bit of data about</p> <p>9 Celebrex was positive in the right direction, it wasn't six</p> <p>10 to two or nine to three, it was all of. All of them showed</p> <p>11 less injury. But the FDA said, No, that's not enough. This</p> <p>12 is my read. If the FDA was sitting here they could say, I</p> <p>13 don't know where this guy was, but this is my read on it. So</p> <p>14 when we went back to the FDA, I went back with Steve Geis,</p> <p>15 they did insist I believe on a clinical end point study that</p> <p>16 actually had the end points as the end point.</p> <p>17 Q. My question is: At the time you went back with Steve Geis</p> <p>18 the drug was already approved, correct?</p> <p>19 A. I think so, Matt, yes.</p> <p>20 Q. So what were you asking for?</p> <p>21 A. The feeling of the people working with the drug, me included,</p> <p>22 was that it was a safer drug, that it made sense</p> <p>23 pathophysiologically, and all these other things I mentioned</p> <p>24 pointed to the fact that it was safer. So the question was,</p> <p>25 What do we need to do to have the FDA change the label for</p>	<p style="text-align: right;">55</p> <p>1 MR. MONTGOMERY: Absolutely.</p> <p>2 THE VIDEOGRAPHER: I'm worried about</p> <p>3 running out in the middle of an answer.</p> <p>4 MR. MONTGOMERY: Sure. Go ahead. Off</p> <p>5 the record.</p> <p>6 THE VIDEOGRAPHER: We are going off the</p> <p>7 record. The time is 10:11 a.m. This is the end of Tape</p> <p>8 No. 1.</p> <p>9 (Recess 10:11-10:26.)</p> <p>10 THE VIDEOGRAPHER: Okay. We are back on</p> <p>11 the record. The time is 10:26 a.m. This is the beginning of</p> <p>12 Tape No. 2.</p> <p>13</p> <p>14 EXAMINATION (Continuing)</p> <p>15 BY MR. MONTGOMERY:</p> <p>16 Q. You understand you're still under oath?</p> <p>17 A. I do.</p> <p>18 Q. All right. Looking at Exhibit 60, do you have it in front of</p> <p>19 you?</p> <p>20 A. Correct.</p> <p>21 Q. All right. On the first page of Exhibit 60 do you see the</p> <p>22 heading Gastrointestinal Risk in the upper left-hand corner?</p> <p>23 A. I do.</p> <p>24 Q. And is that the warning that you were talking about before</p> <p>25 that Searle was trying to have the FDA remove?</p>
<p style="text-align: right;">54</p> <p>1 celecoxib -- what do we have to do to have the FDA change the</p> <p>2 label for celecoxib to say that it's less injurious than</p> <p>3 standard NSAIDs? And that was the question that caused</p> <p>4 Searle to go back to the FDA.</p> <p>5 Q. So Searle was asking the FDA to delete a GI warning from the</p> <p>6 Celebrex label?</p> <p>7 A. I think so. I don't know what the actual form was but it was</p> <p>8 basically every NSAID has had this two to four percent of</p> <p>9 patients taking this drug develop a symptomatic ulcer or a</p> <p>10 complicated ulcer with a one percent or two percent incidence</p> <p>11 of a complicated ulcer and I think Searle was saying, It's</p> <p>12 not true of our drug. And they had a lot of studies, they</p> <p>13 had a lot of data that suggested that it wasn't true, but</p> <p>14 they hadn't done this blinded placebo controlled or whatever</p> <p>15 comparison.</p> <p>16 MR. MONTGOMERY: All right. I'd like to</p> <p>17 show the witness what's previously been marked as Exhibit 60.</p> <p>18 THE WITNESS: (Witness reviewing</p> <p>19 document.)</p> <p>20 MR. MONTGOMERY: While you're looking at</p> <p>21 that, we can let the record reflect that David Goldberger of</p> <p>22 Scott &amp; Scott has appeared on behalf of plaintiffs.</p> <p>23 THE VIDEOGRAPHER: Counsel, because of</p> <p>24 the length of the answers can I suggest that we take a break</p> <p>25 now and change the tape?</p>	<p style="text-align: right;">56</p> <p>1 A. Fair question. I don't know because I'm not overly familiar</p> <p>2 with this format for prescribing information. It does look</p> <p>3 as if this is in a black box and is the GI risk and talks</p> <p>4 about the risk of these events occurring and that they can</p> <p>5 occur with or without symptoms, so I think it is the box that</p> <p>6 they were hoping to have changed by the series of studies</p> <p>7 including the CLASS study.</p> <p>8 Q. And just to be clear, Exhibit 60 is a copy of the Celebrex</p> <p>9 label that we were talking about earlier?</p> <p>10 A. Correct. I don't know -- yes, I'm sorry; that is correct. I</p> <p>11 don't know what the date of this is. Revised in June of '09.</p> <p>12 And I have -- I have not been involved in consulting on this</p> <p>13 matter since 2001 so many things have occurred that I'm not</p> <p>14 aware of because I did not keep up the way I used to with all</p> <p>15 of the literature about it. So -- but this is what you</p> <p>16 described.</p> <p>17 Q. All right. Unfortunately this doesn't have -- Exhibit 60</p> <p>18 doesn't have page numbers so could you turn to the page that</p> <p>19 starts with Section 14.7 of Exhibit 60?</p> <p>20 A. (Witness complies.) Okay.</p> <p>21 Q. All right. Do you see the information on that page regarding</p> <p>22 the CLASS study?</p> <p>23 A. I see it.</p> <p>24 Q. All right. Do you see the discussion of the meeting</p> <p>25 exposure? It's about the third sentence. I'll read it into</p>



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<p style="text-align: right;">57</p> <p>1 the record. "Meeting exposure for Celebrex (N equals 3987)</p> <p>2 and diclofenac (N equals 1196) were nine months while</p> <p>3 ibuprofen (N equals 1985) was six months."</p> <p>4 Do you see that?</p> <p>5 A. I do.</p> <p>6 Q. And as far as you know is that an accurate description of the</p> <p>7 meeting exposure from the CLASS study?</p> <p>8 A. I think it is. I believe it is because I just read it. I</p> <p>9 don't have independent corroboration in my head.</p> <p>10 Q. All right. Earlier you were talking about a presentation you</p> <p>11 made to the FDA on or around 1998; do you remember that?</p> <p>12 A. Yes.</p> <p>13 Q. And you talked about 14 different studies; is that correct?</p> <p>14 A. That's correct.</p> <p>15 Q. And were all those studies about -- or did all those studies</p> <p>16 include Celebrex?</p> <p>17 A. Yes. All right. And the No. 14 was a figure of speech. I</p> <p>18 don't remember exactly how many it was. But if I remember</p> <p>19 there was a series of studies.</p> <p>20 Q. Approximately 14?</p> <p>21 A. Approximately 10. 10 to 14, I don't remember.</p> <p>22 Q. Okay. And then you said those patients represented about</p> <p>23 15,000 patients; is that right?</p> <p>24 A. Well, no. The total number of patients studied for the NDA</p> <p>25 application for Celebrex was 15,000 patients. That included</p>	<p style="text-align: right;">59</p> <p>1 out prematurely because of abdominal pain.</p> <p>2 But if the purpose of the study was to look at your</p> <p>3 blood level, your hemoglobin level or your hematocrit, we</p> <p>4 might keep going. We might say, Well, we're going to keep</p> <p>5 drawing the blood. So a little bit of taking the patient off</p> <p>6 the study or leaving the patient on the study will be related</p> <p>7 to what's the nature of the study.</p> <p>8 Q. With that qualification is it your understanding that these</p> <p>9 10 to 14 studies had information regarding the withdrawal of</p> <p>10 patients taking Celebrex versus NSAIDs?</p> <p>11 A. You know, I'm sure the information was available. I'm not</p> <p>12 sure I saw it. Because I think if you are giving a drug for</p> <p>13 let's say a month and at the end of the month you're doing an</p> <p>14 endoscopy and looking at the number of the ulcers, it's much</p> <p>15 less likely to have somebody drop out than if you're doing a</p> <p>16 six-month or longer study. So I'm sure they have the data.</p> <p>17 I'm positive the data is there. I'm not sure I always saw</p> <p>18 that data.</p> <p>19 Q. Okay. So I'm not asking you whether you saw it or not. Let</p> <p>20 me ask the question again, which is: Is it your</p> <p>21 understanding that in these 10 to 14 studies there was some</p> <p>22 information regarding withdrawals, patient withdrawals both</p> <p>23 in patients that took Celebrex and patients that took other</p> <p>24 NSAIDs?</p> <p>25 A. Yes, there's information. It might be zero, but there was</p>
<p style="text-align: right;">58</p> <p>1 things other than GI studies. It would have included studies</p> <p>2 of blood pressure, edema, cardiovascular effects. I mean, it</p> <p>3 was -- when you develop one of these drugs the reason it's so</p> <p>4 expensive is that you have to do a whole variety of different</p> <p>5 studies of safety and efficacy, so it wasn't all oriented</p> <p>6 towards the GI tract. I think Dr. Needleman's point was they</p> <p>7 looked at a lot of people, 10 times the number of people that</p> <p>8 were approved for the standard -- for the previously approved</p> <p>9 NSAIDs.</p> <p>10 Q. All right. And is it standard practice in clinical trials to</p> <p>11 keep track of -- with people who withdrew from the study</p> <p>12 while it was being conducted?</p> <p>13 A. Yes.</p> <p>14 Q. And is it also standard practice to keep track of why they</p> <p>15 withdrew from the study?</p> <p>16 A. Yes.</p> <p>17 Q. So would most or all of the 10 to 14 studies we're talking</p> <p>18 about have kept track of that information?</p> <p>19 A. It's a fair question, but what -- what is important here is</p> <p>20 that the nature of the study might be such that nobody would</p> <p>21 drop out. So to clarify that. If we were doing a study of</p> <p>22 bleeding and somebody came in and said, I'm having terrible</p> <p>23 abdominal pain, I as a clinician would say, You're off the</p> <p>24 study. I'm not going to keep you on the study, I don't want</p> <p>25 to put you at risk. So that would be a person who dropped</p>	<p style="text-align: right;">60</p> <p>1 information. I'm sure there's information.</p> <p>2 Q. Okay. Are you familiar with the -- generally familiar with</p> <p>3 the design of the CLASS trial?</p> <p>4 A. I am.</p> <p>5 Q. All right. And was it designed as two separate trials? I'm</p> <p>6 sorry. I should have said: Are you familiar with the design</p> <p>7 of the CLASS study?</p> <p>8 A. Yes.</p> <p>9 Q. And was it designed as two separate trials?</p> <p>10 A. No. Let me explain why I say that. When -- I am not a</p> <p>11 clinical trial expert but I've done a lot of clinical trials,</p> <p>12 and -- just like I'm not a statistics expert although I know</p> <p>13 something about statistics. And I don't mean to preach.</p> <p>14 Having said that, the purpose of a clinical trial is to</p> <p>15 answer a question, and if you don't start with the question</p> <p>16 everything deteriorates from there.</p> <p>17 So generally there should be one question that you're</p> <p>18 trying to answer in a trial and I think the question -- there</p> <p>19 was only one question, which was: Is Celebrex less injurious</p> <p>20 in terms of GI complications than other NSAIDs? That was the</p> <p>21 question.</p> <p>22 Q. So that's why you consider it one trial?</p> <p>23 A. Yes.</p> <p>24 Q. Were there two separate arms to the trial?</p> <p>25 A. There were.</p>



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<p style="text-align: right;">61</p> <p>1 Q. And what were they?</p> <p>2 A. One was a comparison of Celebrex at fairly high dose to</p> <p>3 ibuprofen which was selected I believe because it was thought</p> <p>4 to be one of the least injurious NSAIDs, and the other arm</p> <p>5 was a comparison of Celebrex to diclofenac which was selected</p> <p>6 I believe because it was considered to be one of the most</p> <p>7 injurious NSAIDs. And I believe that in the mucosa trial,</p> <p>8 which we discussed earlier, there were 10 NSAIDs that were</p> <p>9 combined. They were never studied independently versus --</p> <p>10 they were never compared one to the other. Because the</p> <p>11 original question in the mucosa trial was does Misoprostol</p> <p>12 change the GI complications in patients taking a variety of</p> <p>13 NSAIDs; in a similar way I think the question here was, in</p> <p>14 patients taking different NSAIDs does Celebrex improve the GI</p> <p>15 outcome? I don't mean to be picking nits, I just think that</p> <p>16 this is important to understand, that I think there was</p> <p>17 really just one primary question and then there --</p> <p>18 Q. Are you --</p> <p>19 A. -- were two arms. I'm sorry.</p> <p>20 Q. I'm sorry. I thought you were done.</p> <p>21 Are you familiar with the term "randomization" as it</p> <p>22 applies to clinical trials?</p> <p>23 A. I am.</p> <p>24 Q. And what is a randomization?</p> <p>25 A. It usually is seen in context with blinding and sometimes</p>	<p style="text-align: right;">63</p> <p>1 months, but patients were allowed to stay on the trial longer</p> <p>2 and some stayed on for up to 13 months. I believe the mean</p> <p>3 was seven months in the ibuprofen group and the median for</p> <p>4 the whole group was nine months, but that's the rough</p> <p>5 numbers. But I think the -- going into it, six months was</p> <p>6 picked as the point at which everybody -- we wanted to get</p> <p>7 everybody through to six months, and that was partially based</p> <p>8 on the mucosa trial which was a six-month trial.</p> <p>9 Q. What's the relevance of the median exposure?</p> <p>10 A. It's just saying that the amount of time patients spent on</p> <p>11 the trial was varied. I don't know -- I mean I know what</p> <p>12 median means, but I don't know precisely how that affects the</p> <p>13 interpretation of the study.</p> <p>14 Q. So if you looked at the -- in the CLASS trial you said median</p> <p>15 is nine months. If that had been 12 months would that have</p> <p>16 given you any more information or would that have impacted</p> <p>17 your analysis?</p> <p>18 A. It would have answered a slightly different question. It</p> <p>19 would have answered the question about what happens over 12</p> <p>20 months as opposed to what happens over nine months. Whether</p> <p>21 it would give you additional information, I don't know.</p> <p>22 Q. All right. Are you familiar with the phrase "primary end</p> <p>23 point" as it applies to clinical studies?</p> <p>24 A. I am.</p> <p>25 Q. And what is a primary end point?</p>
<p style="text-align: right;">62</p> <p>1 with placebo control, although this was not a placebo</p> <p>2 controlled trial. What randomization means is that as a</p> <p>3 patient comes in, he or she is randomly applied to one</p> <p>4 therapy or another therapy so that it decreases the chances</p> <p>5 of bias where the investigator might say, Hmm, this is a</p> <p>6 fairly frail patient, I would prefer to see her on ibuprofen</p> <p>7 than diclofenac. And the investigator might say, Let's put</p> <p>8 this person on -- you know. That would be sort of a</p> <p>9 nonrandomized trial. Randomized trial means that you have</p> <p>10 somebody else adjudicating, Hey, this next patient goes on</p> <p>11 Arm A, which would be the diclofenac arm, Arm B which would</p> <p>12 be the ibuprofen arm or the comparative Celebrex.</p> <p>13 Q. Did each arm of the CLASS study have a separate randomization</p> <p>14 process?</p> <p>15 A. That's a good question and I'm not sure. I believe they did</p> <p>16 but I'm not sure.</p> <p>17 Q. And are there any -- assume for this purpose that they did.</p> <p>18 I can -- I'll show you the protocol in a minute and we can</p> <p>19 talk about it then, but does the two separate randomizations</p> <p>20 have any implication for the statistical analysis of the</p> <p>21 results after the study is done?</p> <p>22 A. I don't know.</p> <p>23 Q. Okay. How long was the CLASS study? I'm sorry; per the</p> <p>24 design?</p> <p>25 A. Okay. Well, the design was to have patients get to six</p>	<p style="text-align: right;">64</p> <p>1 A. When you design a clinical trial, just as you come up with</p> <p>2 one question you want to answer, you say, We wanted to find</p> <p>3 an end point which answers that question. And you put</p> <p>4 statistical bounds on it so that you're fairly sure that when</p> <p>5 you get an answer, if it is statistically significant that</p> <p>6 you can point to it and say, I think there's a real</p> <p>7 difference here.</p> <p>8 Q. What was the primary end point of the CLASS study?</p> <p>9 A. The primary end point of the CLASS study was a GI</p> <p>10 complication, specifically GI bleeding, perforation or GI</p> <p>11 obstruction, and that was the primary -- unless I'm getting</p> <p>12 lost here, that was the primary end point.</p> <p>13 Q. And do you have an understanding of why that was chosen as</p> <p>14 the primary end point?</p> <p>15 A. I do. As I said, short of death, which can result from</p> <p>16 bleeding perforation or obstruction, the -- every patient is</p> <p>17 an individual -- and this is going to sound a little strange</p> <p>18 perhaps, but every patient is an individual. Physicians try</p> <p>19 to group patients because they don't know what else to do, so</p> <p>20 when somebody comes in with flu like symptoms you try to</p> <p>21 group them into a diagnosis of the flu.</p> <p>22 In this instance you try to group patients where</p> <p>23 something has gone amiss with their GI tract into what</p> <p>24 categories can go wrong, and the categories seem to be partly</p> <p>25 from the mucosa trial, partly from my ASGE trials and partly</p>



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<p style="text-align: right;">65</p> <p>1 from 300 other trials that the predominant things that happen 2 of an adverse nature in somebody who is taking NSAIDs in the 3 upper GI tract are bleeding, perforation and obstruction. 4 Therefore, those were the end points selected. 5 They did not select the end point for the primary end 6 point of symptomatic ulcers, and I think it raises -- you 7 know, it's the same issue that I've been talking about 8 repeatedly, which is it's a continuum and if you want to be 9 really, really, really, really sure, take mortality. If you 10 want to be sure just a little short of that, take the three 11 complications. A little short of that you'd include 12 symptomatic ulcers. Because as I said, if I were taking care 13 of you and you had a symptomatic ulcer I would take you off a 14 trial, I wouldn't let you keep going because I would consider 15 that to put you at risk of a real serious complication. But 16 the decision was made and I was not -- to the best of my 17 knowledge I was not part of that decision. That was done 18 before I joined the CLASS group. The decision was made to 19 make those three complications the primary end point and not 20 to include symptomatic ulcers as a primary end point. 21 Q. Do you have an understanding of whether the FDA had an 22 opinion on what the primary end point should be? 23 A. I don't know that. I don't know if the FDA did -- you know, 24 said that they wanted symptomatic ulcers in it or not in it, 25 but they weren't in it, and I don't have a clear answer to</p>	<p style="text-align: right;">67</p> <p>1 should be analyzed after the study's finished? 2 A. I would think so. 3 Q. And why not just get the data and then decide how to analyze 4 it afterwards? 5 A. Well, you could do that if you had very carefully specified 6 your primary and secondary end points. You could get the 7 data and say let's look at the primary end points and 8 secondary end points. They're sort of linked together. If 9 you say the primary end point is to look at serious adverse 10 GI events, then that's what we're going to look at in the two 11 different groups, so they're kind of together. 12 Q. But do you define -- before you start the trial do you define 13 how you're going to analyze the primary end points? 14 A. This is really a statistical question and I am not a 15 statistician, but to the best of my knowledge the answer 16 would be yes. 17 Q. And why is that? 18 A. Because you want to conduct a trial and look at the data to 19 answer the question. You don't want to conduct a trial, look 20 at the data and then decide what kind of questions you want 21 to answer. So in general you would like to design a trial 22 and have the trial then answer the question that you started 23 with. 24 Q. All right. Would you turn to page Bates number ending 850 of 25 Exhibit 61.</p>
<p style="text-align: right;">66</p> <p>1 your question. 2 Q. All right. I want to ask you a question that's specifically 3 about the year 1999 and your understanding at that point. 4 At that point did you have an understanding of whether 5 or not NSAIDs created GI adverse events sooner than Celebrex? 6 A. No. I don't think so. I mean, the way you'd have to answer 7 that would be tough because it would take -- if you're 8 talking about the three events you'd have to do a time to 9 event analysis of how long it's taking for the different 10 groups. If you're trying to look at ulcers you'd have to do 11 serial endoscopies. And that's not so easy to do from an 12 ethical standpoint. You know, an endoscopy every week, 13 that's putting a patient through a lot. So I don't think 14 there was information available about that, to my knowledge. 15 Q. All right. 16 MR. MONTGOMERY: I'd like to show the 17 witness now what is Exhibit 61, has been previously marked as 18 Exhibit 61. 19 Q. (BY MR. MONTGOMERY) Is Exhibit 61 a protocol for the CLASS 20 study? 21 A. It would appear to be, yes. 22 Q. And what's the purpose of a protocol? 23 A. To define how the study is designed and how the study should 24 be conducted. 25 Q. Does a protocol also set forth how the results of the study</p>	<p style="text-align: right;">68</p> <p>1 A. (Witness complies.) Okay. 2 Q. Do you see Section 4.3 on that page? 3 A. Yeah. 4 Q. All right. And it says "Treatment period," correct? 5 A. Correct. 6 Q. And is that a common term when discussing clinical studies? 7 A. Yes. 8 Q. And what does it mean? 9 A. It means that's the period of time that the patients will be 10 exposed to whatever you're going to treat them with while 11 you're looking for the end event. 12 Q. And what was the treatment period in -- per this protocol? 13 A. Oh, I believe it was at least 26 weeks which is six months, 14 up to 52 weeks, it looks like to me. 15 Q. All right. And that just describes the minimum and maximum 16 amount of time that the patients on the study are exposed to 17 the drug, correct? 18 A. Correct. 19 Q. Okay. 20 MR. MONTGOMERY: At this point I'd like 21 to show the witness what's previously been marked as 22 Exhibit 63. 23 MS. McPHEE: I'm sorry; what was the 24 exhibit number? 25 MR. MONTGOMERY: 63. You'll recognize</p>



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<p>69</p> <p>1 it.</p> <p>2 Q. (BY MR. MONTGOMERY) Have you seen Exhibit 63 before?</p> <p>3 A. No, I have not seen this entire exhibit although I have seen</p> <p>4 portions of the exhibit.</p> <p>5 Q. Per the first page it's called an All Committee Manual,</p> <p>6 correct?</p> <p>7 A. Right.</p> <p>8 Q. Do you have an understanding of what an All Committee Manual</p> <p>9 is?</p> <p>10 A. No. I mean it's -- appears to be obvious that it has the</p> <p>11 three committees that we used to help run the trial listed</p> <p>12 and then the references that were sought and used during</p> <p>13 especially the drug safety and monitoring portion.</p> <p>14 Q. But you don't have an understanding of what this particular</p> <p>15 document was to be used for; is that right?</p> <p>16 A. Do you mean the entire document?</p> <p>17 Q. Yeah.</p> <p>18 A. I -- I think I'm confusing the times you're talking about. I</p> <p>19 mean this is -- these are the reports of what happened so I</p> <p>20 don't know --</p> <p>21 Q. Let me clarify then.</p> <p>22 A. Yes, please do.</p> <p>23 Q. I'm not talking about the individual portions of the</p> <p>24 document, which we'll get to in a minute, but the whole</p> <p>25 document itself, Exhibit 63 with all its constituent parts,</p>	<p>71</p> <p>1 the -- I don't understand the drug safety and monitoring</p> <p>2 functions overly well because that's not an expertise of</p> <p>3 mine. There are people who are experts in studying drug</p> <p>4 toxicity. How do you study renal effects? How do you study</p> <p>5 hepatic effects? I know some about it, but I'm not an expert</p> <p>6 about that.</p> <p>7 I am an expert on GI events. And the reason I was in</p> <p>8 this whole trial was GI events. The reason I didn't sit on a</p> <p>9 chair at the gastrointestinal events committee was I didn't</p> <p>10 have time. My other responsibilities in life were -- didn't</p> <p>11 leave me enough time, because it's extremely time-consuming</p> <p>12 to look at each event and then to try to adjudicate whether</p> <p>13 it in fact constitutes one of the complications. And</p> <p>14 although it may not be what anybody wants to hear, in fact,</p> <p>15 these events are not always as easy to say yes or no as you</p> <p>16 might think.</p> <p>17 So the executive committee -- I think I've answered</p> <p>18 your question. I think -- I feel that the executive</p> <p>19 committee had to overlook the trial, be sure nothing had gone</p> <p>20 wrong, be sure the blind hadn't been broken, to find out that</p> <p>21 some center had opened the blind my mistake, and then to see</p> <p>22 if there were any things happening. I mean it's also</p> <p>23 possible the gastrointestinal events committee could have</p> <p>24 found something that was worrisome and gone to the executive</p> <p>25 committee and said, Something is happening and we better stop</p>
<p>70</p> <p>1 do you have an understanding of what purpose it served?</p> <p>2 A. I think so. I think it would -- it talks about what the</p> <p>3 executive committee thought, what the drug safety and</p> <p>4 monitoring board thought and what the GI events committee</p> <p>5 thought. So in that sense I think that's what it is, right.</p> <p>6 Q. And is this a document that would be submitted to the FDA or</p> <p>7 for internal use?</p> <p>8 A. I don't know.</p> <p>9 Q. Okay. Were you on the executive committee of the CLASS</p> <p>10 trial?</p> <p>11 A. I was.</p> <p>12 Q. Were you the chairman of the committee?</p> <p>13 A. I was.</p> <p>14 Q. And what was the function of the executive committee?</p> <p>15 A. The function of the executive committee was really to oversee</p> <p>16 the trial and to -- in the event that something went wrong,</p> <p>17 as I see it, if something went wrong, for example, under drug</p> <p>18 safety and monitoring and if that person had contacted the</p> <p>19 executive committee and saying, We're seeing a signal that</p> <p>20 suggests that something is happening here that we don't like,</p> <p>21 it would have been the executive committee's responsibility</p> <p>22 along with everybody else to say, We better stop the trial</p> <p>23 because we're seeing something that we're worried about.</p> <p>24 And I think that really is the main responsibility of</p> <p>25 the executive committee. Plus to be sure that -- you see,</p>	<p>72</p> <p>1 the trial until we figure out what it is. It could have been</p> <p>2 of any nature. So that's my concept of what an executive</p> <p>3 committee does.</p> <p>4 Q. Okay. Would you take a look at the second and third pages of</p> <p>5 Exhibit 63, please.</p> <p>6 A. Right.</p> <p>7 Q. These would be Bates numbers ending in 099 and 100.</p> <p>8 A. Right.</p> <p>9 Q. Is this a letter that you wrote to James Lefkowitz dated</p> <p>10 February 9th, 2000?</p> <p>11 A. That's correct.</p> <p>12 Q. And why did you write this letter?</p> <p>13 A. It was actually at Dr. Lefkowitz's suggestion and with input</p> <p>14 from him that we clarified the fact that there were these</p> <p>15 committees and so that it was run properly that we had the</p> <p>16 executive committee, the adverse effects committee and the</p> <p>17 drug -- you know, the three, the GI event committee and the</p> <p>18 drug safety monitoring board, and I believe it also -- just</p> <p>19 one second, that the blind had been maintained.</p> <p>20 In other words, I think in any one of these studies, if</p> <p>21 the blind has been opened, it calls immediately into question</p> <p>22 the integrity of the study. Not integrity meaning the</p> <p>23 morality of it, but rather whether you can really count on</p> <p>24 the study. And I was sure -- I said because I was told</p> <p>25 repeatedly that the study was conducted in an exemplary way,</p>



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<p style="text-align: right;">73</p> <p>1 nobody had broken the blind, no idea how any of the groups 2 were doing prior to the study being completed and opened. 3 Q. Okay. Would you take a look at the second paragraph on the 4 first page of your February 9th, 2000 letter. 5 A. Yes. 6 Q. It starts -- the paragraph that starts, "The charter of the 7 executive committee," do you see that? 8 A. Yes, yes. 9 Q. All right. About two-thirds of the way down in that 10 paragraph do you see on the left side you refer to the two 11 CLASS trials? 12 A. Yes. 13 Q. Why did you characterize them as two separate trials in this 14 letter? 15 A. Okay. Just a moment. Let me read that. 16 Q. Sure, take your time. 17 A. (Witness complies.) 18 Okay. You may be asking a question about whether we 19 called it two separate trials. I would say that that wasn't 20 the point of what I was saying. What I was saying was that 21 the gastrointestinal events committee was in fact very, very 22 careful about how they used the definitions that we came up 23 with as to whether to include or not to include a patient as 24 an event. And I will give you a chance to ask me a question 25 if I'm getting it wrong but -- but the point I want to make</p>	<p style="text-align: right;">75</p> <p>1 trial. But again, it sounds like it's simple, but it's 2 simple to somebody who's never done it. To those of us who 3 have actually done it it's almost an -- it's an unanswerable 4 question, and I know that because in that ASGE study I did in 5 1980 it was very difficult. I mean how many units of blood? 6 How about this: A patient comes in and vomits blood 7 but never needs a blood transfusion? Or a patient comes in 8 and has a slightly low hematocrit and blood in their stool, 9 the stool is brown, hematocrit -- the stool hemoccult is 10 positive, but they don't need a blood transfusion. Is that a 11 GI bleed? 12 So the easy ones are easy, the difficult ones are in 13 fact very difficult. And the point I was making there was -- 14 where I say the primary outcome of the trials -- obviously 15 the trial against diclofenac and the trial against 16 ibuprofen -- was the care was taken to review the records of 17 any patient thought to have an ulcer complication, 18 definitions were used and they were stuck to. And again, I 19 tell you that I sat in a room once when I was doing this ASGE 20 trial with hundreds of pounds of paper trying to figure some 21 of this out and we just do the best you can. 22 Q. All right. I think my question is a little simpler, which 23 is: Earlier I think -- I believe you testified that you 24 thought it was a single trial, that the CLASS was a single 25 trial because it was answering one question.</p>
<p style="text-align: right;">74</p> <p>1 is, to you a GI bleed is a GI bleed. To me that's not the 2 case. And I'll give you an example. Somebody who comes in 3 and vomits up a quart of blood and has red blood in their 4 stool, that's a GI bleed. Probably a GI bleed. Could 5 occasionally be something strange like an attachment between 6 the aorta and the small bowel where the blood is coming right 7 out of the aorta through a fistula. But that's going to be 8 very rare. 9 So if somebody vomits blood and they have dark stools 10 or red stools, you would say that's an upper GI bleed. But 11 what about a person who comes in a little light-headed and 12 has black stools which you test and has a little bit of blood 13 in it, but their blood level is normal? Or what about the 14 patient who comes in who vomits up blood and their blood 15 level is normal but they fainted? The point I'm making is 16 that it's a whole continuum of signs and symptoms that 17 patients present with and it's not easy to say whether 18 something is or is not an event. And this is critical 19 because as you know, the number of events was actually very 20 small, so just one or two events could have the effect of 21 changing the outcome or interpretation of the study. 22 So this issue about the committee adhered strictly to 23 the definitions and the precise definitions were used, I was 24 involved with the evolution of those definitions, as I 25 remember. I certainly was involved with that in the mucosa</p>	<p style="text-align: right;">76</p> <p>1 A. Yeah. 2 Q. And here you refer to it as two trials, and I'm wondering why 3 that is? 4 A. Oh, I -- it's a fair enough question. I think it's two 5 trials together to answer one question. That's why. I mean 6 I think it was that. I understand why you asked it but 7 that's what I think is the answer. But the point of the 8 paragraph -- 9 Q. Right. I understand. 10 A. -- is what I went into. 11 Q. Okay. When you wrote this letter February 9th, 2000, had the 12 executive committee finished its work? 13 A. This is 10 years ago and I don't exactly remember. I believe 14 that is the case. 15 Q. Okay. 16 A. And I think the purpose of this was to codify that no -- 17 blind wasn't broken, we were very careful about monitoring 18 for serious data and also very careful with the GI events. 19 Q. All right. Did the executive committee have a charter? 20 A. It did. 21 Q. All right. And you see in the first sentence of the third 22 paragraph of your February 9th, 2000 letter it says that "The 23 executive committee adhered to its charter"? 24 A. I believe that's right. 25 Q. And -- you think that's accurate?</p>



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<p style="text-align: right;">77</p> <p>1 A. Yes.</p> <p>2 Q. So there were no violations in the charter that you're aware</p> <p>3 of?</p> <p>4 A. That is correct.</p> <p>5 Q. Was the charter ever amended?</p> <p>6 A. I don't remember.</p> <p>7 Q. Okay. Can you turn to the fourth page of Exhibit 63, Bates</p> <p>8 number ending 101. I don't think you're there.</p> <p>9 A. I'm sorry. Oh, the signatures?</p> <p>10 Q. 101.</p> <p>11 A. Okay, just a minute. This one.</p> <p>12 Q. Yes. Is this the signature page of the executive committee</p> <p>13 charter?</p> <p>14 A. It looks that way to me, yes.</p> <p>15 Q. And is that your signature at the top?</p> <p>16 A. It is.</p> <p>17 Q. All right. Unfortunately the copy of the executive committee</p> <p>18 charter that's in this document is partial, some pages were</p> <p>19 missing. So I'm going to show you what's previously been</p> <p>20 marked as Exhibit 69 to fill in the blanks.</p> <p>21 Does this appear to you to be an unsigned version of</p> <p>22 the executive committee charter?</p> <p>23 A. It does.</p> <p>24 Q. All right. Would you turn to Page 2 of the document.</p> <p>25 A. Okay.</p>	<p style="text-align: right;">79</p> <p>1 approve the EC charter?</p> <p>2 A. Yes.</p> <p>3 Q. All right. Going back above to Section 3.1, do you see in</p> <p>4 the bottom bullet point, No. 2, it says "To prepare the</p> <p>5 primary manuscript of each study"?</p> <p>6 Do you see that?</p> <p>7 A. Yes.</p> <p>8 Q. Is it your understanding that at least at the time this</p> <p>9 charter was finalized that the executive committee was</p> <p>10 expecting to write a separate manuscript for each arm of the</p> <p>11 CLASS study?</p> <p>12 A. No.</p> <p>13 Q. Okay. Why does it say that?</p> <p>14 A. Oh, excuse me. I didn't see the part that says "of each</p> <p>15 study." I think that it's making recommendations regarding</p> <p>16 the publication of data collected so it's making</p> <p>17 recommendations to prepare the primary manuscript of each</p> <p>18 study. It looks as if it's dividing it up into two studies</p> <p>19 but that was not my -- not my knowledge of it at the time. I</p> <p>20 missed that.</p> <p>21 Q. Okay. Could you turn the page to Page 3 of Exhibit 69. Do</p> <p>22 you see Section 5.3, Voting, there?</p> <p>23 A. Yes.</p> <p>24 Q. Was Dr. Lefkowitz a member of the executive committee?</p> <p>25 A. I believe he was a nonvoting member but I don't exactly</p>
<p style="text-align: right;">78</p> <p>1 Q. In Exhibit 69. Do you see Section 3.1 there, The</p> <p>2 Responsibilities of the Executive Committee?</p> <p>3 A. Yes.</p> <p>4 Q. Would you take a look at those responsibilities. My question</p> <p>5 is: To your recollection did the executive committee fulfill</p> <p>6 those responsibilities?</p> <p>7 A. Okay. I read it. I'm sorry; ask the question again.</p> <p>8 Q. Does Section 3.1 here set out the responsibilities of the</p> <p>9 executive committee?</p> <p>10 A. It does.</p> <p>11 Q. And did the executive committee fulfill those</p> <p>12 responsibilities?</p> <p>13 A. To the best of my knowledge, yes.</p> <p>14 Q. Okay. Do you see Section 3.2 below that?</p> <p>15 A. Yes.</p> <p>16 Q. "Functions of the EC"?</p> <p>17 A. Yes.</p> <p>18 Q. Does EC stand for executive committee?</p> <p>19 A. It does.</p> <p>20 Q. Do you see the first bullet point there says, "Review and</p> <p>21 approve the EC charter"?</p> <p>22 A. Yes.</p> <p>23 Q. That's the document we're looking at, correct?</p> <p>24 A. Yes.</p> <p>25 Q. And did you in fact, as the executive committee, review and</p>	<p style="text-align: right;">80</p> <p>1 remember. He was certainly the Searle representative and he</p> <p>2 certainly was very much involved with this trial. I don't</p> <p>3 remember whether he was a formal member of the committee. He</p> <p>4 may have been a nonvoting Searle representative.</p> <p>5 Q. All right. Is there any -- well, can you look at Section 5.3</p> <p>6 on Page 3 of Exhibit 69? Is there anything in there that</p> <p>7 would indicate that Dr. Lefkowitz was not allowed to vote?</p> <p>8 A. (Witness complies.)</p> <p>9 I don't think it addresses it one way or the other. It</p> <p>10 certainly does not say that he was not allowed to vote. I</p> <p>11 don't think it addresses it.</p> <p>12 Q. All right. Would you turn the page, please, Page 4 of</p> <p>13 Exhibit 69. Do you see Section 5.4, "Procedures for</p> <p>14 recommendations to Searle," at the top of the page?</p> <p>15 A. I do.</p> <p>16 Q. All right. I'm going to read this section into the record.</p> <p>17 "Duly voted and passed EC recommendations will be transferred</p> <p>18 in writing to Searle within seven working days of the meeting</p> <p>19 of which the recommendation was formulated and passed."</p> <p>20 Do you see that?</p> <p>21 A. I do.</p> <p>22 Q. And to your knowledge did the executive committee comply with</p> <p>23 this portion of the charter?</p> <p>24 A. I -- to my knowledge we did, but --</p> <p>25 Q. I'm sorry.</p>



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<p style="text-align: right;">81</p> <p>1 A. I'm sorry. Excuse me.</p> <p>2 Q. Go ahead.</p> <p>3 A. But I'm not positive that it was always in writing. I think</p> <p>4 it was -- I don't know if it was always in writing. I can't</p> <p>5 remember.</p> <p>6 Q. Okay. Do you have any recollection of any recommendations</p> <p>7 that the executive committee made to Searle that weren't in</p> <p>8 writing?</p> <p>9 A. No.</p> <p>10 Q. Okay.</p> <p>11 A. And furthermore, I don't have any recommendations made to</p> <p>12 Searle by the executive committee that were sort of in any</p> <p>13 way pertinent. I mean it's not as if we, Uh-oh, we've got</p> <p>14 something going on here, I don't want to put it in writing,</p> <p>15 I'll tell you; that to my knowledge never happened. So I</p> <p>16 don't think the executive committee -- earlier we saw</p> <p>17 somewhere that it would look at the data safety and efficacy</p> <p>18 and would alert Searle if something was happening. I don't</p> <p>19 think that ever happened.</p> <p>20 Q. All right. Let's look at Exhibit 5 -- I'm sorry; Section 5.6</p> <p>21 of Exhibit 69. Do you see that, "Summary notes"?</p> <p>22 A. Yes.</p> <p>23 Q. I'm going to read the first sentence into the record. It</p> <p>24 says, "Summary notes are prepared for each meeting of the EC</p> <p>25 and distributed in a timely manner after each meeting and</p>	<p style="text-align: right;">83</p> <p>1 Q. -- which is: Do you have a recollection of any specific</p> <p>2 instances where there was a meeting of the executive</p> <p>3 committee but minutes were not created?</p> <p>4 A. I do not.</p> <p>5 Q. Okay. If I ever ask a question you don't understand, let me</p> <p>6 know and I'll try it again.</p> <p>7 A. No, you're doing fine.</p> <p>8 Q. Can you look at the last page of Exhibit 69? Do you see at</p> <p>9 the top of that page it talks about, "Exemptions by the EC</p> <p>10 chairperson for conflicts of interest"?</p> <p>11 A. Yes.</p> <p>12 Q. You were the chairperson, correct?</p> <p>13 A. Correct.</p> <p>14 Q. Did you grant any exemptions?</p> <p>15 A. I believe that each of the three people on the committee were</p> <p>16 paid consultants to Searle and were exempted and I don't</p> <p>17 remember if that was done in writing, but I think -- to the</p> <p>18 best of my knowledge we never discussed any parts of</p> <p>19 remuneration or compensation, but as far as I know Gerry</p> <p>20 Faich and Lee Simon were consultants to Searle and were part</p> <p>21 of the executive committee and that was fine with me.</p> <p>22 Q. Were you compensated for serving on the executive committee?</p> <p>23 A. Only in the sense that I each month would total up the number</p> <p>24 of hours I spent working on the CLASS trial and would bill</p> <p>25 Searle pursuant of all the financial data that exists</p>
<p style="text-align: right;">82</p> <p>1 reviewed and approved at the subsequent meeting."</p> <p>2 Do you see that?</p> <p>3 A. I do.</p> <p>4 Q. And to your knowledge did the executive committee comply with</p> <p>5 that?</p> <p>6 A. I don't remember.</p> <p>7 Q. Do you remember summary notes being created?</p> <p>8 A. To some degree but I don't exactly remember that minutes were</p> <p>9 collected and circulated. They may well have? I just -- in</p> <p>10 the middle of all the things that were going on I just don't</p> <p>11 remember.</p> <p>12 Q. Do you remember any specific instances where minutes -- first</p> <p>13 of all, strike that question.</p> <p>14 So do you understand summary notes to be the same thing</p> <p>15 as meeting minutes?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. And do you have any specific recollection of any</p> <p>18 instances where there was a meeting of the executive</p> <p>19 committee but where minutes or summary notes were not</p> <p>20 created?</p> <p>21 A. A lot of negatives in that, but I do not remember whether</p> <p>22 every meeting had minutes and whether every set of minutes</p> <p>23 was circulated.</p> <p>24 Q. Right. I'm asking a slightly different question now --</p> <p>25 A. Right, please.</p>	<p style="text-align: right;">84</p> <p>1 somewhere, and that would have included the time that I</p> <p>2 was -- that I spent on the executive committee. But I don't</p> <p>3 remember that as being a large amount of time.</p> <p>4 Q. Did you have any participation in the conduct of the CLASS</p> <p>5 study other than serving on the executive committee?</p> <p>6 A. You know, not really because I should have been on the GI</p> <p>7 events committee because that is truly where my expertise is,</p> <p>8 but I couldn't be because of time constraints. So I would</p> <p>9 say if you want to know where my time came out, it was in the</p> <p>10 area of the functioning of the executive committee, not in</p> <p>11 the data drug safety and monitoring. And it wasn't in the</p> <p>12 events committee because those folks were spending hundreds</p> <p>13 of hours looking at every case and trying -- I occasionally</p> <p>14 spoke to them about it, they would consult with me because of</p> <p>15 my expertise in GI bleeding clinically, but I would say most</p> <p>16 of it was the executive committee, my participation.</p> <p>17 Q. So just to clarify, as far as you understand it, you were</p> <p>18 compensated for serving on the executive committee of the</p> <p>19 CLASS study?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. Do you remember the GM article we talked about</p> <p>22 earlier?</p> <p>23 A. Yes.</p> <p>24 Q. Were you -- you were one of the authors of that letter -- I'm</p> <p>25 sorry; that article, correct?</p>



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<p style="text-align: right;">85</p> <p>1 A. I was.</p> <p>2 Q. And were you compensated for being an author of that article?</p> <p>3 A. I don't remember. I would probably say no, that that was</p> <p>4 not -- it was sort of the end of the trial and here was the</p> <p>5 paper and I was not compensated specifically for that, no.</p> <p>6 To the best of my knowledge.</p> <p>7 Q. Okay. Would you turn to Page -- we're going back to the big</p> <p>8 document now, Exhibit 63. Would you turn to page Bates</p> <p>9 number ending 9105 of Exhibit 63.</p> <p>10 A. (Witness complies.)</p> <p>11 Q. All right. Are these the minutes of a March 3rd, 1999</p> <p>12 executive committee meeting?</p> <p>13 A. So it would appear, yes.</p> <p>14 Q. Okay. Now, having looked at this do you recall whether or</p> <p>15 not you saw the minutes after each meeting?</p> <p>16 A. Yes, I guess. There's a lot of paper, but yes, I would say</p> <p>17 yes, I was aware of this.</p> <p>18 Q. All right. Would you turn the page, please, to Bates number</p> <p>19 ending 106 of Exhibit 63?</p> <p>20 A. Yes.</p> <p>21 Q. Are these the minutes of the June 6th, 1999 executive</p> <p>22 committee meeting?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. Turn the page again to the page Bates ending 107 of</p> <p>25 Exhibit 63. Are these the minutes of a September 21st, 1999</p>	<p style="text-align: right;">87</p> <p>1 A. I do.</p> <p>2 Q. All right. Take a look at the second paragraph there and</p> <p>3 then let me know if that refreshes your recollection --</p> <p>4 A. Okay.</p> <p>5 Q. -- about the censoring rule.</p> <p>6 A. (Witness complies.)</p> <p>7 Yes. I mean I was right. That's exactly what it's</p> <p>8 talking about. It's the fear that you're going to confound</p> <p>9 the data because of therapy the person was on prior to coming</p> <p>10 on the trial, an illness they may have suffered. So you want</p> <p>11 to take that out as long as possible but you don't want to</p> <p>12 miss events related to the study so it's a bit of a quandary.</p> <p>13 You know, you want to go longer or endoscope the people and</p> <p>14 say, Okay, she's clean, she doesn't have an ulcer, she can</p> <p>15 come on. But if you don't do that -- and there are reasons</p> <p>16 not to do that, as I said. Endoscopy, even as an old</p> <p>17 endoscopist who's done maybe 25,000 endoscopies, endoscopy is</p> <p>18 not entirely safe and any time you do it on a patient you're</p> <p>19 putting him to a risk. So it's a ying and a yang of we would</p> <p>20 prefer to have an endoscopy but that carries its own risk.</p> <p>21 So you say, Okay, we're going to go seven days. We're</p> <p>22 going to say that -- that's what this is saying, we'll go</p> <p>23 seven days and any event that occurs before then will be not</p> <p>24 considered, and then apparently it was changed to two days in</p> <p>25 the article you showed me.</p>
<p style="text-align: right;">86</p> <p>1 executive committee meeting?</p> <p>2 A. Yes.</p> <p>3 Q. Would you look at the third paragraph in the discussion</p> <p>4 summary?</p> <p>5 A. Yes.</p> <p>6 Q. And do you see a reference to "the new 48-hour censoring</p> <p>7 rules"?</p> <p>8 A. Yes.</p> <p>9 Q. And do you know what that refers to?</p> <p>10 A. You know, I don't exactly remember. I know the concept is</p> <p>11 this: If patients come into a trial, the cleanest way to do</p> <p>12 the trial is to endoscope them and say they're clear of</p> <p>13 ulcers and then start them on the drug and really endoscope</p> <p>14 them and say whether or not they have an ulcer. If you don't</p> <p>15 have either of those the question comes up as to whether the</p> <p>16 person came on to the study and had an ulcer caused by a</p> <p>17 different drug they were on at a remote period and how do you</p> <p>18 deal with that, and I think -- I think that's what the</p> <p>19 censoring rule was. I would like to see the definition of</p> <p>20 censoring rules. I don't remember precisely what that</p> <p>21 referred to.</p> <p>22 Q. Why don't you take a look at the protocol, Exhibit 61 I</p> <p>23 believe, Bates number ending 857 of Exhibit 61.</p> <p>24 A. Just a moment. I have it.</p> <p>25 Q. All right. You see Section 5.5 on that page?</p>	<p style="text-align: right;">88</p> <p>1 Q. Okay. So just to clarify: Per the protocol, any ulcer</p> <p>2 complications that happened in the study within seven days of</p> <p>3 a patient starting the study were censored and didn't count</p> <p>4 basically, correct?</p> <p>5 A. Correct.</p> <p>6 Q. And then later that was changed from seven days to two days,</p> <p>7 correct?</p> <p>8 A. Correct.</p> <p>9 Q. And why was that?</p> <p>10 A. I don't remember.</p> <p>11 Q. All right. We'll look at some minutes in a minute.</p> <p>12 A. Okay.</p> <p>13 Q. I'll follow up with that.</p> <p>14 For now let's turn the page, please, to Bates number</p> <p>15 ending 108 of Exhibit 63.</p> <p>16 A. (Witness complies.)</p> <p>17 Q. And are these minutes of a December 2nd, 1999 meeting of the</p> <p>18 executive committee, the DSMV, the GEC, and people from</p> <p>19 Searle and Pfizer?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. And why was there a joint meeting of all the</p> <p>22 committees?</p> <p>23 A. Getting all these people together in person is a challenge.</p> <p>24 Most of us were very busy -- as a matter of fact, correct,</p> <p>25 every one of us was very busy and getting us to travel to one</p>



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<p style="text-align: right;">89</p> <p>1 spot is -- was difficult, and therefore, when we had a chance</p> <p>2 to get everybody together that was a good thing. I don't</p> <p>3 remember whether the whole meeting was everybody together or</p> <p>4 whether it was -- and therefore the executive committee was</p> <p>5 represented by myself, Simon and Faich, the DSMV by Makuch</p> <p>6 and Pincus and Faich, et cetera. But I think that's what</p> <p>7 happened. I think we all got together to review what was</p> <p>8 happening.</p> <p>9 Q. I guess my question is why the previous minutes were of</p> <p>10 individual meetings of just the executive committee. This is</p> <p>11 a joint meeting of all three committees plus some other</p> <p>12 people. Do you have an understanding of why this particular</p> <p>13 meeting was everyone?</p> <p>14 A. I don't.</p> <p>15 Q. Okay. Was this the last meeting of the executive committee?</p> <p>16 A. I don't know.</p> <p>17 Q. Okay. At this meeting did the executive committee and the</p> <p>18 other committees decide to stop the CLASS study earlier than</p> <p>19 the protocol called for?</p> <p>20 A. I believe that's true.</p> <p>21 Q. And why did they do that, or you do that?</p> <p>22 A. Right. I believe what had happened was that there was a</p> <p>23 dramatic drop off in the number of events occurring -- still</p> <p>24 blinded, to my knowledge still blinded, and it looked as if</p> <p>25 we were getting one or two, or we were getting an event every</p>	<p style="text-align: right;">91</p> <p>1 UGI event censoring rules."</p> <p>2 A. Yes.</p> <p>3 Q. Would you read that paragraph to yourself and let me know</p> <p>4 when you're done.</p> <p>5 A. (Witness complies.) Okay.</p> <p>6 Q. All right. Having looked at that, does that refresh your</p> <p>7 memory about why the censoring rule was changed from a week</p> <p>8 to 48 hours?</p> <p>9 A. No, because -- may I just --</p> <p>10 Q. Sure. Go ahead.</p> <p>11 A. Because it looked as if it was saying -- it was taking as a</p> <p>12 given that it was going to be 48 hours and then saying, Okay,</p> <p>13 in light of the 48 hours, any event occurring within the</p> <p>14 first 48 hours of the first dose of study medication I guess</p> <p>15 would not be allowed and any event occurring more than</p> <p>16 48 hours after the last dose, except that any event occurring</p> <p>17 within two weeks would be looked at by the gastrointestinal</p> <p>18 events committee.</p> <p>19 Q. All right. And at this time --</p> <p>20 A. But that doesn't -- I'm sorry. It doesn't address the</p> <p>21 question of why they went from seven days to two days.</p> <p>22 Q. Okay. And you don't know?</p> <p>23 A. I don't remember.</p> <p>24 Q. Okay. At this time period, so 1999, did you have an</p> <p>25 understanding whether or not NSAIDs were more likely to cause</p>
<p style="text-align: right;">90</p> <p>1 one or two months and that it was going to take a long time</p> <p>2 to get -- I think the original -- there was a number of</p> <p>3 patients stipulated as being the total number we wanted to</p> <p>4 get and we weren't quite there, short by I think three, but</p> <p>5 that it looked like it was going to take a long time to get</p> <p>6 those three. And I think that's what we're saying: "The</p> <p>7 review of the clinical events show the observed study 35</p> <p>8 deviated from prediction with no events for three months and</p> <p>9 102, only one event in the past two months."</p> <p>10 So for that reason it was decided to stop the study.</p> <p>11 THE VIDEOGRAPHER: Counsel, the page is</p> <p>12 partially blocking. Yeah, just a little bit lower. Thanks.</p> <p>13 Q. (BY MR. MONTGOMERY) All right. Do you recall any specific</p> <p>14 executive committee meetings after December 2nd, 1999?</p> <p>15 A. I do not.</p> <p>16 Q. Do you remember the executive committee doing anything as a</p> <p>17 committee after deciding to terminate the study?</p> <p>18 A. I don't remember. Again, this was in a time when lots of</p> <p>19 things were going on and I just don't remember.</p> <p>20 Q. Okay. Would you turn to page Bates ending 127 of Exhibit 63.</p> <p>21 A. Yes.</p> <p>22 Q. All right. The top of the page reads "The historical</p> <p>23 incidence," do you see that?</p> <p>24 A. Yes.</p> <p>25 Q. If you look at the second paragraph there that starts, "The</p>	<p style="text-align: right;">92</p> <p>1 ulcer complications within the first seven days than</p> <p>2 Celebrex?</p> <p>3 A. No, I do not remember that.</p> <p>4 Q. Do you have an understanding about that now?</p> <p>5 A. I do not.</p> <p>6 Q. Okay.</p> <p>7 A. If you look at the -- if you look at the demography of what</p> <p>8 happens with these events, and having done it myself because</p> <p>9 I've endoscoped lots of people on trials and clinical people,</p> <p>10 you wouldn't expect too many things to happen within just a</p> <p>11 few days. Now, that's -- that was the whole issue is if it</p> <p>12 happened, you know, within a few days was it related to</p> <p>13 previous stuff or was it related to the current drugs?</p> <p>14 Are we done with this thing for now?</p> <p>15 Q. Yes, for now.</p> <p>16 MR. MONTGOMERY: At this point I'd like</p> <p>17 to show the witness what's been previously marked as</p> <p>18 Exhibit 66.</p> <p>19 Q. (BY MR. MONTGOMERY) Is this the final report for the CLASS</p> <p>20 study?</p> <p>21 A. Yes.</p> <p>22 Q. And have you seen it before?</p> <p>23 A. I -- I'm sorry. I believe I have.</p> <p>24 Q. What's the purpose of a final report?</p> <p>25 A. To record what happened in the study so that later if you</p>



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<p style="text-align: right;">93</p> <p>1 need to go back and figure out what happened you'd have one</p> <p>2 place to go. It's probably never easier to put this together</p> <p>3 than right after the study is done. You wait two or three</p> <p>4 years it's more and more difficult to figure out what</p> <p>5 happened. So it's -- the obvious would be it's a way of</p> <p>6 explaining how the trial was conducted and what happened and</p> <p>7 how the data was interpreted.</p> <p>8 Q. And is it your understanding that a final report is for</p> <p>9 internal use or to give to the FDA?</p> <p>10 A. I don't know. I know the FDA gets everything. Whether they</p> <p>11 get this report or not, I don't know. But data-wise they get</p> <p>12 all the data.</p> <p>13 Q. Okay. On the first page do you see the study dates?</p> <p>14 A. I do.</p> <p>15 Q. All right. And do you see the date March 17, 2000 there?</p> <p>16 A. (Witness nods head up and down.)</p> <p>17 Q. You have to answer audible.</p> <p>18 A. Yes. I'm sorry. I do.</p> <p>19 Q. What does that date represent?</p> <p>20 A. I don't know. I would assume looking at this that it's the</p> <p>21 date of the last -- the date in which we would still accept a</p> <p>22 patient; that after that we would say the study is over, so</p> <p>23 studies were accepted until that day. That's what I would</p> <p>24 assume from looking at this.</p> <p>25 Q. Okay. Would you turn to the fifth page of Exhibit 66 Bates</p>	<p style="text-align: right;">95</p> <p>1 you want the study groups to be comparable. So, for example,</p> <p>2 you would not want -- if you take a study A versus B, you</p> <p>3 would not want 90 percent of the patients in A to be male and</p> <p>4 10 percent of the patients in B to be male. You'd like the</p> <p>5 groups to be comparable. And a lot of time was spent on this</p> <p>6 trial to look at the demographics and assure the fact that</p> <p>7 the different groups were comparable in terms of age,</p> <p>8 diagnosis, underlying risk factors, et cetera.</p> <p>9 My concept is that the question arose as to why did</p> <p>10 some of the NSAID comparators stop having adverse events?</p> <p>11 What happened? I mean is it known that you can take a drug</p> <p>12 and if you get by six months that you somehow are now</p> <p>13 protected against an adverse event? And I think the answer</p> <p>14 is no to that. I don't think that's the case. I don't think</p> <p>15 anybody has any evidence to that being true.</p> <p>16 So I feel that you want to be as sure as possible that</p> <p>17 as the study moves along the groups are comparable and</p> <p>18 therefore that conclusions one draws for any time period are</p> <p>19 relevant because the groups were comparable. And my concept</p> <p>20 of what happened was that during the six months there was a</p> <p>21 change in the nature of the groups because people with</p> <p>22 symptoms and symptomatic ulcers were being dropped</p> <p>23 disproportionately from the NSAID arms of the study rather</p> <p>24 than the Celebrex arms, and therefore, at six months, if</p> <p>25 you've gotten rid of the patients who have symptoms and the</p>
<p style="text-align: right;">94</p> <p>1 number ending 116.</p> <p>2 A. (Witness complies.) Okay.</p> <p>3 Q. Do you see the Statistical Methods at the top of the page?</p> <p>4 A. I do.</p> <p>5 Q. All right. Under the first bullet do you see the paragraph</p> <p>6 that reads, "The primary reason"?</p> <p>7 A. Yes.</p> <p>8 Q. All right. Can you read that to yourself and let me know</p> <p>9 when you're done.</p> <p>10 A. Yes, I will. (Witness complies.) Okay. I've read it.</p> <p>11 Q. Does that paragraph describe the primary reason for analysis</p> <p>12 at six months?</p> <p>13 A. I believe it does.</p> <p>14 Q. Okay. And can we refer to that generally as informative</p> <p>15 censoring?</p> <p>16 A. Partly. I mean it's partly informative censoring and it's</p> <p>17 partly talking about the confounding effect of taking low</p> <p>18 dose aspirin, which is not informative censoring as I see it.</p> <p>19 Q. Let's just talk about the --</p> <p>20 A. So it's both.</p> <p>21 Q. -- informative censoring part.</p> <p>22 A. Okay.</p> <p>23 Q. Can you explain to me in your own words what informative</p> <p>24 censoring refers to in this context of the CLASS study?</p> <p>25 A. Yes. So it gets back to this question about -- in a study</p>	<p style="text-align: right;">96</p> <p>1 patients who have symptomatic ulcers in let's say the</p> <p>2 diclofenac group, that therefore, the chance of that person</p> <p>3 developing an ulcer complication in the ensuing six months of</p> <p>4 that group of patients is different.</p> <p>5 In other words, you have depleted the susceptibles.</p> <p>6 The susceptibles are the people with ulcers and with ulcer</p> <p>7 symptoms and they're out of the study. And surely we know</p> <p>8 that -- I told you that if you have 100 people taking NSAIDs,</p> <p>9 not all of them develop symptoms and not all of them develop</p> <p>10 symptomatic ulcers and surely not all of them develop ulcer</p> <p>11 complications. There are some people who can take these</p> <p>12 drugs with impunity and they get by fine. But there are some</p> <p>13 people in whom they do develop symptoms and those people were</p> <p>14 being -- as I understand it, those people were not</p> <p>15 proportionate in the Celebrex versus the NSAID groups, and</p> <p>16 therefore, the data after six months was not comparing</p> <p>17 comparable groups.</p> <p>18 Sorry. That's a winding answer, but...</p> <p>19 Q. What you just said, though, that's your understanding of the</p> <p>20 informative censoring theory?</p> <p>21 A. That's right.</p> <p>22 Q. Okay. All right. So correct me if I'm wrong. You said it's</p> <p>23 the withdrawal of people that either get a symptomatic ulcer</p> <p>24 or a GI symptom, correct?</p> <p>25 A. Correct. And I think -- please, I'm sorry.</p>



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<p style="text-align: right;">97</p> <p>1 Q. So with regard to the symptomatic ulcers, can you correct for</p> <p>2 that by using a combined end point that uses complicated</p> <p>3 ulcers as well as symptomatic ulcers?</p> <p>4 A. Can you correct for it? Well, you certainly can look at the</p> <p>5 data. I mean you can change the end point from just</p> <p>6 complications, you know, perforation, bleeding and</p> <p>7 obstruction, and you can add symptomatic ulcers. Yes, that</p> <p>8 would be one way to say, We have a little better feel for</p> <p>9 what's happening.</p> <p>10 Q. Right. I mean to the extent that you add symptomatic ulcers</p> <p>11 to the end point then --</p> <p>12 A. Yes, you're right.</p> <p>13 Q. -- the withdrawal of them is no longer relevant as to</p> <p>14 informative censoring, correct?</p> <p>15 A. It's already considered as a data point.</p> <p>16 Q. Right. So let me say it again for the record to be clear.</p> <p>17 So if you used a combined end point of complicated</p> <p>18 ulcers and symptomatic ulcers, then the withdrawal of people</p> <p>19 that got symptomatic ulcers is no longer a concern as to</p> <p>20 informative censoring?</p> <p>21 A. What you're saying is logical. I am not completely sure that</p> <p>22 I understand the definition of informative censoring. It's</p> <p>23 something that I'm -- I'm not a statistician and I'm not a</p> <p>24 clinical trial designer and so I'm not completely comfortable</p> <p>25 with the definition of that. So, for example, if -- it may</p>	<p style="text-align: right;">99</p> <p>1 A. Correct.</p> <p>2 Q. Okay. But pursuant to your understanding of informative</p> <p>3 censoring then, would the inclusion of symptomatic ulcers as</p> <p>4 a combined end point correct for any informative censoring</p> <p>5 due to withdrawal of people that had symptomatic ulcers?</p> <p>6 MR. WEISS: Object to the form of the</p> <p>7 question.</p> <p>8 THE WITNESS: I'm afraid you have to ask</p> <p>9 the question again.</p> <p>10 Q. (BY MR. MONTGOMERY) All right. Let me ask you again.</p> <p>11 Pursuant to your understanding of informative</p> <p>12 censoring, would including symptomatic ulcers in a combined</p> <p>13 end point correct for any informative censoring caused by the</p> <p>14 withdrawal of patients who suffered symptomatic ulcers?</p> <p>15 MR. WEISS: Object to the form of the</p> <p>16 question.</p> <p>17 THE WITNESS: Well, I was thinking that</p> <p>18 you still wind up at the end of six months having dropped out</p> <p>19 a bunch of patients. You would have to say that you would</p> <p>20 have to look after six months at end points including</p> <p>21 symptomatic ulcers because you have just dropped a bunch of</p> <p>22 the people who could get -- who could get the complicated</p> <p>23 ulcer, right?</p> <p>24 Q. (BY MR. MONTGOMERY) Right. But if you include a symptomatic</p> <p>25 ulcer as part of your end point, it doesn't matter whether</p>
<p style="text-align: right;">98</p> <p>1 be that if a patient -- I don't know what it means. It</p> <p>2 doesn't even logically make sense to me. What does informed</p> <p>3 censoring mean? If it means the patient has a symptom and is</p> <p>4 then informed that that might be an ulcer developing and they</p> <p>5 drop, I guess that would be one definition of it; that is,</p> <p>6 you're taking out patients partly because you're informing</p> <p>7 them and they're saying, Well, gee, if this symptom might be</p> <p>8 an ulcer, I'd like to come off the trial.</p> <p>9 I think one of the problems with this trial, with</p> <p>10 recent trials, is that because of the earlier work that was</p> <p>11 done, partially by me and partially by hundreds of other</p> <p>12 people, we got a pretty good idea for what happens to these</p> <p>13 patients. And people got a little skittish about putting</p> <p>14 people on these trials. You know, you don't want a doctor to</p> <p>15 put just anybody on, and if somebody defined like, My</p> <p>16 goodness, the guy's 88, he's had a known previous heart</p> <p>17 attack, he's had bleeding ulcers, I don't want him on the</p> <p>18 trial, that's what happened increasingly in these trials</p> <p>19 compared to trials that were done 20 years before. But my</p> <p>20 concept would be that if you include symptomatic ulcers then</p> <p>21 you're correcting for that part of the informative censoring,</p> <p>22 but I'm not an expert in that.</p> <p>23 Q. Okay. So you have some understanding of informative</p> <p>24 censoring but you're not sure that it's a comprehensive</p> <p>25 understanding?</p>	<p style="text-align: right;">100</p> <p>1 you got a complicated ulcer or a symptomatic ulcer, correct?</p> <p>2 It still counts as one, so --</p> <p>3 A. But you're asking does that affect informative censoring?</p> <p>4 Q. Well, does it correct for it to the extent that there is</p> <p>5 informative censoring that you can ascribe to people dropping</p> <p>6 out because of symptomatic ulcers?</p> <p>7 A. Well, I guess my answer would be yeah, as long as you</p> <p>8 continue looking at the symptoms.</p> <p>9 Q. Okay.</p> <p>10 A. If you say, Hey, in the first six months we're going to look</p> <p>11 at symptoms and complications, then at the end of six months</p> <p>12 we're just going to look at complications, I would say no,</p> <p>13 you still have the problem because you've taken out all the</p> <p>14 symptomatic ulcers. If you say, From six to 12 months or</p> <p>15 beyond six months we're going to look at symptomatic ulcers</p> <p>16 and ulcer complications, I think it does, logically to me,</p> <p>17 does go some way to correcting for the problem.</p> <p>18 Q. Okay. And is it your understanding that that's what you in</p> <p>19 fact did, you looked at the combined end point for the entire</p> <p>20 study period?</p> <p>21 A. Yes.</p> <p>22 Q. So --</p> <p>23 A. I'm not saying when we did, but at some point the combined</p> <p>24 end point was looked at at six months and for the entire</p> <p>25 study period.</p>



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<p style="text-align: right;">101</p> <p>1 Q. And so pursuant to what you just testified for, then that, to</p> <p>2 your understanding, would correct for any informative</p> <p>3 censoring that you can ascribe to symptomatic ulcers?</p> <p>4 MR. WEISS: Objection to the form of the</p> <p>5 question.</p> <p>6 MR. BUSHOFSKY: Objection to the form of</p> <p>7 the question.</p> <p>8 THE WITNESS: I suspect I'm not exactly</p> <p>9 following where everybody is.</p> <p>10 MR. BUSHOFSKY: You can go ahead and</p> <p>11 answer.</p> <p>12 THE WITNESS: So I would say that it</p> <p>13 would -- it would help the portion of informative censoring</p> <p>14 which is occurring because of symptomatic ulcers, yes, it</p> <p>15 would improve that problem.</p> <p>16 Q. (BY MR. MONTGOMERY) Okay. Now let's talk about the censoring</p> <p>17 that's caused by the GI symptoms.</p> <p>18 The informative censoring theory with regard to GI</p> <p>19 symptoms is premised on the idea that people that suffer GI</p> <p>20 symptoms would have been more likely to go on and suffer</p> <p>21 ulcer complications, correct?</p> <p>22 MR. WEISS: Objection to the form of the</p> <p>23 question.</p> <p>24 THE WITNESS: I would look at it --</p> <p>25 again, I'm looking at it back the other way; that if the</p>	<p style="text-align: right;">103</p> <p>1 MR. WEISS: Objection to the form of the</p> <p>2 question.</p> <p>3 THE WITNESS: Yes.</p> <p>4 Q. (BY MR. MONTGOMERY) Okay. And what was that based on?</p> <p>5 A. The same thing I've been saying, which is, looked at it the</p> <p>6 other way, when you look at patients who have the</p> <p>7 complications and you say that, let's say 50 percent of them</p> <p>8 have had symptoms, if you eliminate patients with symptoms</p> <p>9 you're going to be reducing the number of patients that</p> <p>10 develop any complication.</p> <p>11 And therefore, if you're eliminating all the people</p> <p>12 with symptoms, you're removing the susceptible group. And in</p> <p>13 addition to that, I told you earlier that I think symptoms</p> <p>14 are, in the purpose of sitting in this room, are easy to</p> <p>15 define. They're not that easy to define when you're dealing</p> <p>16 with a patient. Every one of these patients is different.</p> <p>17 Picture somebody in your family and you're asking them</p> <p>18 questions and having them go around in circles about whether</p> <p>19 you have it.</p> <p>20 So I think that if you do a careful question that</p> <p>21 people with these ulcer complications, probably even more</p> <p>22 than 40 or 50 percent have symptoms, antecedent symptoms in</p> <p>23 the 30 days prior to presenting with a complication.</p> <p>24 THE VIDEOGRAPHER: Counsel, there's about</p> <p>25 10 minutes left on the tape.</p>
<p style="text-align: right;">102</p> <p>1 people have complications that somewhere between, you know,</p> <p>2 30 and 90 percent of them have symptoms, and therefore if you</p> <p>3 eliminate all the patients that have symptoms you are going</p> <p>4 to reduce the number of people with complications.</p> <p>5 Q. (BY MR. MONTGOMERY) Okay. But now I'm asking you to look at</p> <p>6 it my way, which is: For the informative censoring to be a</p> <p>7 valid theory with regard to GI symptoms, is it necessary that</p> <p>8 people that suffer GI symptoms would have been more likely to</p> <p>9 go on and suffer an ulcer complication?</p> <p>10 MR. WEISS: Objection to the form of the</p> <p>11 question.</p> <p>12 THE WITNESS: Yes.</p> <p>13 Q. (BY MR. MONTGOMERY) All right. And at the time of this</p> <p>14 report, were you -- did you have an understanding that that</p> <p>15 was in fact true?</p> <p>16 MR. BUSHOFSKY: Objection; form.</p> <p>17 THE WITNESS: I'm sorry. "True" meaning?</p> <p>18 Q. (BY MR. MONTGOMERY) Let me just say it a different way.</p> <p>19 At the time of the final report, for example, did you</p> <p>20 have an understanding that in fact people who suffered</p> <p>21 symptom -- I'm sorry.</p> <p>22 At the time of the final report did you have an</p> <p>23 understanding that people who in fact suffered GI symptoms</p> <p>24 would in fact be more likely to go on and get an ulcer</p> <p>25 complication?</p>	<p style="text-align: right;">104</p> <p>1 MR. MONTGOMERY: Okay.</p> <p>2 Q. (BY MR. MONTGOMERY) Do you know whether any empirical</p> <p>3 analysis was done of the CLASS data to see if in fact the</p> <p>4 people in the study who suffered GI symptoms were more likely</p> <p>5 to suffer ulcer complications?</p> <p>6 MR. WEISS: Objection to the form of the</p> <p>7 question.</p> <p>8 THE WITNESS: That's a reasonable</p> <p>9 question but by definition can't be answered, because if they</p> <p>10 were taken off the study then you don't know what would</p> <p>11 happen to them and that's what happened.</p> <p>12 Q. (BY MR. MONTGOMERY) But not everybody that suffered GI</p> <p>13 symptoms withdrew from the study, correct?</p> <p>14 A. I don't know that. I don't remember that. Perhaps you can</p> <p>15 find that somewhere. I know everybody with a symptomatic</p> <p>16 ulcer withdrew from the trial. I don't remember how many</p> <p>17 people with symptoms withdrew and how many people with</p> <p>18 symptoms stayed on the trial.</p> <p>19 Q. I think we're going to go back to Exhibit 61 to answer that</p> <p>20 question but it's going to take me a second to find it.</p> <p>21 All right. I think it's on page Bates ending 855 of</p> <p>22 Exhibit 61.</p> <p>23 A. I have 855.</p> <p>24 Q. All right. Do you see the first full paragraph at the top</p> <p>25 there?</p>



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<p style="text-align: right;">105</p> <p>1 A. I'm sorry. Oh, 854. Excuse me. I was on the wrong page. 2 Yes. 3 Q. All right. Do you see the first full paragraph that starts 4 "GI complaints"? 5 A. Oh, this -- I'm sorry. This document is out of order. It's 6 not -- maybe my brain is out of order. I am now on 855. I'm 7 sorry. "GI complaints will be collected and analyzed." 8 Yes, I see that paragraph. 9 Q. Why don't you read that paragraph to yourself and let me know 10 when you're done. 11 A. (Witness complies.) Okay. 12 Q. Does this refresh your memory about whether or not people 13 with GI symptoms would remain in the study? 14 A. Well, I think what it says is that patients who report GI 15 symptoms, if they're endoscoped to have an x-ray and there's 16 no evidence of an ulcer, can then participate, but it doesn't 17 address the issue about how often it happened. They may 18 continue to participate, but somebody may have said, Look, I 19 don't care whether you saw an ulcer or not, I want to come 20 off the study because I don't feel well. And I don't know 21 how often that happened. 22 Q. Okay. We'll pursue that later on in the final report then. 23 All right. Going back to final report, Exhibit 66, please. 24 A. Yes. 25 THE VIDEOGRAPHER: About seven minutes.</p>	<p style="text-align: right;">107</p> <p>1 Q. And when did that happen? 2 A. I don't remember. 3 Q. Did it happen before or after the unblinding of the data? 4 A. I think actually before, but I don't exactly remember, but 5 sometime in that period of time it was said, We'll do a 6 six-month analysis. 7 Q. Before the data was unblinded, why would you think that a 8 six-month analysis was a good idea? 9 A. Because the -- it was clear that something had happened. 10 That was the whole reason for stopping the trial that 11 something had changed and I think that the idea would be, 12 Let's look at six months. Let's look at the rest of it. I 13 mean we got to figure out why there seems to be a change in 14 the curve. 15 Q. And is that something that the executive committee 16 communicated to Pharmacia? 17 A. I don't remember that. I think it was pretty obvious to 18 everybody, and I don't remember specifically communicating 19 that to Pharmacia. 20 Q. Well, if you're going to do a six-month analysis, was the 21 executive committee going to do it itself -- 22 A. Oh, no. 23 Q. -- or was it going to have Pharmacia do it? 24 A. Oh, no. I'm sorry. No, it would have Pharmacia do it but I 25 think Pharmacia also wanted to do it. So -- I don't remember</p>
<p style="text-align: right;">106</p> <p>1 MR. MONTGOMERY: Let's just go off the 2 record and change the tape. 3 THE VIDEOGRAPHER: We are going off the 4 record. The time is 11:39 a.m. This is the end of Tape 5 No. 2. 6 (Recess 11:39-11:46.) 7 THE VIDEOGRAPHER: All right. We are 8 back on the record. The time is 11:46 a.m. This is the 9 beginning of Tape No. 3. 10 11 EXAMINATION (Continuing) 12 BY MR. MONTGOMERY: 13 Q. You understand you're still under oath? 14 A. I do. 15 Q. All right. Let's go back to Exhibit 66. We were talking 16 about the page Bates number ending 116 that discusses 17 informative censoring. Do you recall that? 18 A. Yes, I do. 19 Q. All right. So part of informative censoring, the discussion 20 here is as a reason for the six-month analysis? 21 A. Yes. 22 Q. And did the executive committee ever make a decision that the 23 six-month analysis -- or that a six-month analysis should be 24 performed of the CLASS data? 25 A. I believe we did.</p>	<p style="text-align: right;">108</p> <p>1 that we told them to do something that they wanted to do too, 2 they just did it. 3 Q. All right. So going back to this page, you said the reasons 4 that are enumerated we talked about before, there's 5 informative censoring and then there's aspirin use as well, 6 correct? 7 A. Correct. 8 Q. Are there any other aspects or results of the trial that 9 justify a six-month analysis? 10 MR. WEISS: Sorry. Could you just repeat 11 that question? 12 (Question on Page 108, Lines 8 13 through 9, read by the 14 reporter.) 15 MR. MONTGOMERY: Let me ask the question 16 again because I didn't mean to say adjustments. Did I say 17 that? 18 THE REPORTER: That's what I heard. 19 MR. MONTGOMERY: That's okay. 20 Q. (BY MR. MONTGOMERY) Were there any other aspects or results 21 of the CLASS study that justified a six-month analysis? 22 MR. WEISS: Object to the form of the 23 question. 24 THE WITNESS: It was my understanding 25 from the get-go that it would be analysis done at six months,</p>



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<p style="text-align: right;">109</p> <p>1 before even the trial occurred that there would be an</p> <p>2 analysis at six months. And then there was the issue about</p> <p>3 why it had changed, what had happened, and wanting to look</p> <p>4 back over the first six months versus the additional data.</p> <p>5 But you also mentioned aspirin, and I don't think aspirin is</p> <p>6 part of -- the problem with aspirin is not part of the</p> <p>7 informative censoring as I understand. So you kind of put</p> <p>8 that in your lead in to the question.</p> <p>9 Q. (BY MR. MONTGOMERY) Let me ask it a different way then.</p> <p>10 Is aspirin a different reason besides informative</p> <p>11 censoring that you believe the data from the first six months</p> <p>12 of the study is superior to the data after six months?</p> <p>13 MR. WEISS: Object to the form of the</p> <p>14 question.</p> <p>15 THE WITNESS: No, I don't think so, at</p> <p>16 least not as I understand it. The issue with aspirin --</p> <p>17 should we talk about that for a moment or do you want to do</p> <p>18 that later?</p> <p>19 Q. (BY MR. MONTGOMERY) Not really. Okay.</p> <p>20 A. Well, you know.</p> <p>21 Q. All right. Then is it your understanding that as a result of</p> <p>22 the informative censoring that the data -- the results of the</p> <p>23 CLASS study are better before six months than after six</p> <p>24 months?</p> <p>25 MR. WEISS: Object to the form of the</p>	<p style="text-align: right;">111</p> <p>1 censoring or whether there were other reasons for people</p> <p>2 dropping out.</p> <p>3 For example, lack of efficacy. I think there was some</p> <p>4 mention made that -- and I haven't read about this recently,</p> <p>5 but that the ibuprofen wasn't working for patients with</p> <p>6 arthritis and therefore they were taken off the study. So</p> <p>7 that -- that was another reason that the groups were changing</p> <p>8 at six months but not related to informative censoring</p> <p>9 because of symptoms. That's the best I can come up with.</p> <p>10 Q. (BY MR. MONTGOMERY) Let me try this a different way: Is it</p> <p>11 your understanding that as a result of informative censoring</p> <p>12 the data after six months from the CLASS trial is more biased</p> <p>13 than the data before six months?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. Other than informative censoring, do you have any</p> <p>16 reason to believe -- I'm sorry.</p> <p>17 Do you have any other reason besides informative</p> <p>18 censoring to believe that the data after six months was more</p> <p>19 biased than the data before six months?</p> <p>20 A. Well, the other factor would be lack of efficacy of the drug</p> <p>21 from a rheumatologic standpoint, and therefore people with</p> <p>22 worse arthritis -- and one of the factors in GI bleeding that</p> <p>23 we learned from these previous studies I told you about is</p> <p>24 that the patient's underlying condition is related to the</p> <p>25 risk of bleeding and is related to the outcome of the</p>
<p style="text-align: right;">110</p> <p>1 question.</p> <p>2 THE WITNESS: Yes, that's correct.</p> <p>3 Q. (BY MR. MONTGOMERY) Okay. Other than informative censoring</p> <p>4 is there any reason to believe that the data after six months</p> <p>5 is better than the data -- let me do it again.</p> <p>6 Other than informative censoring is there any reason</p> <p>7 that you know of to believe that the data before six months</p> <p>8 is better than the data after six months?</p> <p>9 MR. WEISS: Object to the form of the</p> <p>10 question.</p> <p>11 THE WITNESS: The only thing that occurs</p> <p>12 to me is the fact that the benchmark that we have for these</p> <p>13 studies is in fact six months, and I think subsequent to the</p> <p>14 CLASS trial, which of course doesn't answer your question</p> <p>15 directly, that's been borne out that I think most of the</p> <p>16 trials have in fact been six months. So in other words, what</p> <p>17 I'm saying is I think I, for example, am most comfortable</p> <p>18 with six months of data. We did that in the mucosa trial and</p> <p>19 at six months in the CLASS trial I was comfortable with that.</p> <p>20 I don't know of any other -- unless I'm blocking it out, I</p> <p>21 don't know of any other reason than informed censoring -- it</p> <p>22 was that -- it was that patients were dropping out of the</p> <p>23 trial in disproportionate numbers in the first six months</p> <p>24 such that the groups were no longer comparable. I'm trying</p> <p>25 to remember in my brain whether that's all informative</p>	<p style="text-align: right;">112</p> <p>1 bleeding episode, and therefore somebody with worse arthritis</p> <p>2 for whom the ibuprofen wasn't working might come off the</p> <p>3 study. And that might be somebody who in fact was at</p> <p>4 increased susceptibility.</p> <p>5 So the informative censoring I would say would be the</p> <p>6 symptoms; dropping the patients off of the study because they</p> <p>7 weren't responding to the medication would have the effect of</p> <p>8 potentially dropping patients with worse underlying arthritis</p> <p>9 who might also be at increased risk of developing a</p> <p>10 complication.</p> <p>11 Q. Okay. So other than informative censoring and the efficacy</p> <p>12 issue that you just described, do you have any reason to</p> <p>13 believe that the data after six months from the CLASS study</p> <p>14 was more biased than the data before six months?</p> <p>15 A. No.</p> <p>16 Q. Okay. Would -- does the fact that patients were required to</p> <p>17 take a minimum of six months of the drug make the six-month</p> <p>18 data more reliable than the entire study data?</p> <p>19 MR. WEISS: Object to the form of the</p> <p>20 question.</p> <p>21 THE WITNESS: Well, let me think. Well,</p> <p>22 I don't see why that would be because you would have the</p> <p>23 first six months data on the people who continued to be on</p> <p>24 six months anyway. I mean I told you that I'm comfortable</p> <p>25 with six months but I don't see -- I don't see -- if you had</p>



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<p style="text-align: right;">113</p> <p>1 all the data you would know what happened in six months. So</p> <p>2 I'm not sure exactly what the question was but it's not clear</p> <p>3 to me.</p> <p>4 Q. (BY MR. MONTGOMERY) All right. Let me ask it again.</p> <p>5 A. Okay.</p> <p>6 Q. The patients -- in order to be counted in the study, patients</p> <p>7 had to take whatever drug they were on for at least six</p> <p>8 months, correct?</p> <p>9 A. Correct.</p> <p>10 MR. WEISS: Object to the form of the</p> <p>11 question.</p> <p>12 MR. BUSHOFSKY: Objection.</p> <p>13 Q. (BY MR. MONTGOMERY) And is there any reason why that fact</p> <p>14 alone would make the analysis of the six-month data superior</p> <p>15 to the entire data set?</p> <p>16 MR. WEISS: Object to the form of the</p> <p>17 question.</p> <p>18 THE WITNESS: Well, you know, it -- from</p> <p>19 a nonexpert in statistics and nonexpert in clinical trial</p> <p>20 design, which I am purporting to be, it would make better</p> <p>21 sense that if everybody made it to six months, we'll look at</p> <p>22 six months. Rather than people who made it to eight months,</p> <p>23 nine months, 12 months, you know -- so in that sense I'm</p> <p>24 comfortable with the first six months of data.</p> <p>25 Q. (BY MR. MONTGOMERY) My question is not, A, whether you're</p>	<p style="text-align: right;">115</p> <p>1 A. Yes.</p> <p>2 Q. All right. And I'd like you to take a look on Table 1, the</p> <p>3 bottom, the number on the bottom right-hand corner 0.037; do</p> <p>4 you see that?</p> <p>5 A. I do.</p> <p>6 Q. Can you tell me what that number represents?</p> <p>7 A. Well, with my earlier disclaimers about statistics, I guess</p> <p>8 it's the P value for the 26-week group rate comparing</p> <p>9 celecoxib to diclofenac and ibuprofen for both together.</p> <p>10 Q. And that's in patients not taking aspirin during the first</p> <p>11 six months; is that right?</p> <p>12 A. No, no. Where -- I don't know that that's the case.</p> <p>13 Q. Just take a look at Table 1, where it says Table 1 at the</p> <p>14 top.</p> <p>15 A. Right.</p> <p>16 Q. Summary of CSUGIE incidence for six months.</p> <p>17 A. I see that, but I don't see where the -- oh, no. I'm sorry.</p> <p>18 Excuse me. I see it now.</p> <p>19 Q. That's no problem.</p> <p>20 A. All patients and patients not taking aspirin, yes. So it is</p> <p>21 statistically significant for both groups below .05, P value</p> <p>22 of .05, okay.</p> <p>23 Q. So this is -- just to restate: That result shows that there</p> <p>24 was a statistically significant difference between Celebrex</p> <p>25 and the combined NSAIDs in the first six months in the</p>
<p style="text-align: right;">114</p> <p>1 comfortable, or B, about seven or nine months or 10 months.</p> <p>2 My question is very specific as to: Does the fact that there</p> <p>3 was a minimum treatment period of six months make the</p> <p>4 six-month analysis in any way better or more reliable than</p> <p>5 the entire data set based on that fact alone?</p> <p>6 MR. WEISS: Object to the form of the</p> <p>7 question.</p> <p>8 THE WITNESS: You know, I -- I have to</p> <p>9 say I don't know. I don't know the answer to that. It's a</p> <p>10 fair question but I don't know the answer.</p> <p>11 Q. (BY MR. MONTGOMERY) Let me ask you a different way then.</p> <p>12 Do you have any reason to believe that just because</p> <p>13 there was a six-month minimum treatment period that that</p> <p>14 would make the six-month analysis any better than the entire</p> <p>15 data set analysis?</p> <p>16 MR. WEISS: Object to the form of the</p> <p>17 question.</p> <p>18 THE WITNESS: No. I don't. I don't.</p> <p>19 Q. (BY MR. MONTGOMERY) All right. Can you turn to Page -- let's</p> <p>20 go to page Bates number ending 117 of Exhibit 66.</p> <p>21 A. Okay.</p> <p>22 Q. Do you see Tables 1 and 2 on that page?</p> <p>23 A. I do.</p> <p>24 Q. All right. And do these summarize some of the results of the</p> <p>25 CLASS study?</p>	<p style="text-align: right;">116</p> <p>1 subgroup of patients taking aspirin, right?</p> <p>2 A. Not taking aspirin.</p> <p>3 Q. I'm sorry. Let me say it again.</p> <p>4 That number shows that there's a statistically</p> <p>5 significant difference between Celebrex and the combined</p> <p>6 NSAIDs in the first six months in patients not taking</p> <p>7 aspirin, correct?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. Now let's look at Table 2. Do you see that that's --</p> <p>10 has the results from the entire study period?</p> <p>11 A. Yes.</p> <p>12 Q. All right. I'd like you to take a look at the same result in</p> <p>13 the lower right-hand corner, .185; do you see that?</p> <p>14 A. Yes, I do.</p> <p>15 Q. And that's not statistically significant, correct?</p> <p>16 A. That is correct.</p> <p>17 Q. And so for the entire study period in patients not taking</p> <p>18 aspirin, there was no statistically significant difference</p> <p>19 between Celebrex and the combined NSAIDs, correct?</p> <p>20 A. I guess that's true, yes.</p> <p>21 Q. All right. And then on -- take a look at the next page,</p> <p>22 please, Bates ending 11 --</p> <p>23 A. Although I --</p> <p>24 Q. Sure.</p> <p>25 A. It's not exactly what my memory is. I'd like to -- let me</p>



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<p>117</p> <p>1 read the bottom of that table.</p> <p>2 Q. Sure.</p> <p>3 A. Okay. All right. It doesn't change what you said.</p> <p>4 Q. Okay. Would you take a look at the next page, Bates ending</p> <p>5 118 of Exhibit 66.</p> <p>6 A. Okay.</p> <p>7 Q. Do you see there are two more tables there, Table 3 and</p> <p>8 Table 4?</p> <p>9 A. I do.</p> <p>10 Q. And those are more summary results of the study?</p> <p>11 A. Correct.</p> <p>12 Q. All right. So all the tables that we've looked at have</p> <p>13 comparisons between diclofenac specifically and Celebrex,</p> <p>14 don't they?</p> <p>15 A. Yes.</p> <p>16 Q. All right. And so in total there's eight different</p> <p>17 comparisons in the tables we just looked at between Celebrex</p> <p>18 specifically and diclofenac, correct?</p> <p>19 A. Yes.</p> <p>20 Q. All right. And are any of those comparisons statistically</p> <p>21 significant?</p> <p>22 A. Nope.</p> <p>23 Q. Okay.</p> <p>24 A. That's not the way I read it.</p> <p>25 Q. Okay. Would you turn to page Bates ending 120 of Exhibit 66,</p>	<p>119</p> <p>1 had terrible headaches on a drug they'd be off the study. I</p> <p>2 mean that -- and that would cause a bias. Perhaps you're</p> <p>3 trying to pick something which is obvious, but...</p> <p>4 Q. No, that's fine. All right. Would you take a look at</p> <p>5 dyspepsia?</p> <p>6 A. Right.</p> <p>7 Q. Adverse events for Celebrex?</p> <p>8 A. Yes.</p> <p>9 Q. And that's 16.5, correct?</p> <p>10 A. Yes.</p> <p>11 Q. And do you know what that number represents? Is it a</p> <p>12 percentage?</p> <p>13 A. I believe it's a percent of patients.</p> <p>14 Q. Okay. Would you turn the page now to Table 9.</p> <p>15 A. Okay.</p> <p>16 Q. And Table 9 display adverse events causing withdrawal with</p> <p>17 incidents greater than one percent in any treatment group?</p> <p>18 A. Yep.</p> <p>19 Q. Okay. And do you see, let's see, under dyspepsia for</p> <p>20 Celebrex --</p> <p>21 A. Right.</p> <p>22 Q. -- it's 3.8 percent?</p> <p>23 A. Right.</p> <p>24 Q. So does that mean that, comparing these two numbers, that</p> <p>25 somewhat over 12 percent of the people who suffered dyspepsia</p>
<p>118</p> <p>1 please.</p> <p>2 A. (Witness complies.)</p> <p>3 Q. Do you see Table 8 at the bottom?</p> <p>4 A. Yes.</p> <p>5 Q. All right. And does Table 8 display the five most frequently</p> <p>6 reported adverse events for the entire study period?</p> <p>7 A. Yes.</p> <p>8 Q. And one of those events is a URTI; is that right?</p> <p>9 A. Yes.</p> <p>10 Q. What is that?</p> <p>11 A. I think it's upper respiratory tract infection, but I don't</p> <p>12 know. TGDMA. I'm sorry; that means too many abbreviations.</p> <p>13 I think it would be okay to write out the word. So I assume</p> <p>14 this is an upper respiratory tract infection.</p> <p>15 Q. Let's just look at headache, for example, then.</p> <p>16 A. Okay.</p> <p>17 Q. We both at least know what that is, right?</p> <p>18 A. I think so.</p> <p>19 Q. Okay. First of all, the adverse events in Table 8 are for</p> <p>20 the entire study period, correct?</p> <p>21 A. Correct.</p> <p>22 Q. And is there any reason to believe that the adverse events</p> <p>23 for headache, for example, became biased at all after six</p> <p>24 months?</p> <p>25 A. Only in the sense that if the person in the first six months</p>	<p>120</p> <p>1 as an adverse event stayed in the study, or at least didn't</p> <p>2 withdraw as a result of dyspepsia?</p> <p>3 A. Let me see if I agree with you about that.</p> <p>4 So Table 8 shows that in the entire study 16 percent of</p> <p>5 people reported dyspepsia on celecoxib, and Table 9 shows</p> <p>6 that in the entire -- I assume it's the entire study, it</p> <p>7 doesn't say, that 4.3 percent of patients on Celebrex came</p> <p>8 off the study because of dyspepsia.</p> <p>9 Q. Actually I believe the number is 3.8.</p> <p>10 A. Oh, excuse me -- 3.8, right, correct.</p> <p>11 Q. Okay.</p> <p>12 A. Okay.</p> <p>13 Q. So my question is then: Does that indicate to you that there</p> <p>14 were people who had dyspepsia in the study that didn't</p> <p>15 withdraw because of dyspepsia?</p> <p>16 A. Well, I'm not sure that's true. And what I mean is events</p> <p>17 causing withdrawal, so you could say that 3.8 percent of</p> <p>18 people on Celebrex came off the trial because of dyspepsia,</p> <p>19 but they might have come off the trial for something else.</p> <p>20 In other words, if a person with -- but come off the trial</p> <p>21 because of diarrhea. So in other words, I'm saying I'm not</p> <p>22 completely clear that because you have the event and because</p> <p>23 you come off the event you can exactly say that's the same</p> <p>24 thing. It's saying that 16 percent of people had dyspepsia,</p> <p>25 3.8 percent of people withdrew because of dyspepsia, but is</p>



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<p style="text-align: right;">121</p> <p>1 it possible that a bunch of those people with dyspepsia 2 withdrew but not because of the dyspepsia, they withdrew 3 because of a gastric ulcer or abdominal pain? 4 So that's why I'm saying I can't make the simple 5 mathematical jump that you proposed. 6 Q. Let me ask it in a more common sense way. 7 Based on these numbers, would you expect that there 8 were people that completed the study despite suffering 9 dyspepsia at some point during? 10 MR. WEISS: Object to the form of the 11 question. 12 THE WITNESS: You know, because of what 13 I'm saying I don't know that I can say that. I don't know 14 that. 15 Q. (BY MR. MONTGOMERY) Okay. 16 A. That's a fair question, but I don't think I can look at this 17 data and tell you that. 18 Q. All right. Could you look at page Bates ending 145 of 19 Exhibit 66. 20 A. (Witness complies.) Okay. 21 Q. Do you see the bottom section discusses the treatment period? 22 A. Yes. 23 Q. And according to the final report what's the treatment 24 period? 25 A. Excuse me one second. Are these duplexed? I got these a</p>	<p style="text-align: right;">123</p> <p>1 who came in, 1600 were withdrawn and of those adverse -- 2 Q. You don't have to read all the numbers if you don't want to. 3 A. Okay. 4 Q. But generally speaking, does Figure 7 A show what happened to 5 all the people that entered the study? 6 A. Yes, I think so. 7 Q. Okay. At the bottom it says? N equals 4573 patients 8 completing six months." 9 Do you see that? 10 A. Yes. 11 Q. And what does that mean? 12 A. That takes the boxes, the three boxes that say N equals 2376, 13 1148 and 1049, that adds up to 4573. 14 Q. So does that mean that 4573 patients completed at least six 15 months of the study? 16 A. That's what it looks like to me. 17 Q. But some of them would have gone on to have more than six 18 months of exposure, correct? 19 A. Correct. 20 Q. Okay. And can you look at page Bates number ending 170 of 21 Exhibit 66. 22 A. Right. 23 Q. And do you see Figure 7 B there? 24 A. I do. 25 Q. And so Figure 7 A that we just looked at, does that show the</p>
<p style="text-align: right;">122</p> <p>1 little screwed up. Just give me one second. Okay. I'm not 2 sure that's in order. Excuse me. So the treatment period. 3 So what is the question, please? 4 Q. Pursuant to the final report what is the treatment period? 5 A. It was the period during which the medication was taken. 6 Q. And what was that? 7 A. Well, at least six months and for some people longer than six 8 months, or until the trial concluded. 9 Q. All right. Would you turn to page Bates ending 168 of 10 Exhibit 66. 11 A. (Witness complies.) Okay. 12 Q. Do you see Figure 7 A? 13 A. I do. 14 Q. And what does Figure 7 A show? 15 A. So it looks at what happened to patients coming in, where 16 they went in the first six months, and it shows that there 17 were a total of 8059 patients randomized, almost all of 18 those, 7968 took the study medication. They were divided up 19 into celecoxib, diclofenac and ibuprofen in the numbers 20 shown, approximately 4,000, 2,000, 2,000. It shows that 2300 21 of the 3900 completed six months with celecoxib. 1148 22 completed six months on diclofenac and 1049 completed six 23 months on ibuprofen. And I don't have a calculator with me 24 but I don't know the percentages of that from this. And then 25 we looked at -- of the people who, for example, on Celebrex</p>	<p style="text-align: right;">124</p> <p>1 disposition of patients just for the first six months? 2 A. Yes. 3 Q. And Figure B shows the same information but for the entire 4 study period, correct? 5 A. Yes. 6 Q. At the bottom there it says "N equals 3409 patients 7 completing the study." 8 Do you see that? 9 A. I do. 10 Q. And what does that represent? 11 A. The number of people who made it through the entire study 12 period which means they came off because of an adverse event 13 or they completed at least six months and then went sometime 14 beyond that which was I believe unspecified, or they made it 15 to 13 months and -- or beyond 12 months and they were taken 16 off the study, or the study closed after they had completed 17 six months. 18 Q. Okay. And the fact that you did a six-month analysis of the 19 data doesn't change the fact that only 3409 patients 20 completed the study, correct? 21 MR. WEISS: Object to the form of the 22 question. 23 THE WITNESS: I'm sorry; ask the question 24 again. 25 Q. (BY MR. MONTGOMERY) Sure. The fact that you chose to perform</p>



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<p>125</p> <p>1 a six-month analysis doesn't change the fact that 3409</p> <p>2 patients completed the study?</p> <p>3 A. No.</p> <p>4 MR. WEISS: Same objection.</p> <p>5 Q. (BY MR. MONTGOMERY) All right. Would you look at page Bates</p> <p>6 number ending 177 of Exhibit 66.</p> <p>7 A. Okay.</p> <p>8 Q. Do you see Figure 8 A?</p> <p>9 A. I do.</p> <p>10 Q. All right. In the lower right-hand portion of Figure 8 A do</p> <p>11 you see, "N equals 260, reviewed by all GEC members"?</p> <p>12 A. I'm sorry. No, I don't see that. Where is that?</p> <p>13 Q. You have Figure 8 A, right?</p> <p>14 A. I'm at Figure 8 A.</p> <p>15 Q. The lower -- on the right side of it there's -- there are</p> <p>16 three boxes; do you see that?</p> <p>17 A. Yeah.</p> <p>18 Q. The top box says --</p> <p>19 A. Oh, 260 reviewed by all GEC members. But I don't know what</p> <p>20 that is yet so let me look and just see. So potential</p> <p>21 complications in 1100 people. In 900 they were reviewed by</p> <p>22 one person and in 260 they were reviewed by everybody. Of</p> <p>23 the 900 almost all were felt to not be events and only one</p> <p>24 made it across. Okay.</p> <p>25 Q. Okay. So what does that box mean, "N equals 260 reviewed by</p>	<p>127</p> <p>1 A. Well, no. The GEC, entire GEC reviewed those. One member at</p> <p>2 least reviewed the other thousand as well.</p> <p>3 Q. All right. Let me put it -- or correct it then.</p> <p>4 So does this mean that the entire GEC reviewed the</p> <p>5 records of 260 patients?</p> <p>6 A. That's correct.</p> <p>7 Q. Okay. Can you turn to Bates number ending 288, please, of</p> <p>8 Exhibit 66.</p> <p>9 A. Okay.</p> <p>10 Q. Do you see Table 10b?</p> <p>11 A. Oh, 288. Excuse me. I thought you meant 188. Table 10b,</p> <p>12 okay.</p> <p>13 Q. And does Table 10b disclose the adverse events with incidence</p> <p>14 greater than or equal to three percent in any treatment group</p> <p>15 for the entire study period?</p> <p>16 A. Yes.</p> <p>17 Q. All right. Is there any reason to believe that the</p> <p>18 information set forth in this table is in any sense more</p> <p>19 reliable at six months rather than in the entire study</p> <p>20 period?</p> <p>21 MR. WEISS: Object to the form of the</p> <p>22 question.</p> <p>23 THE WITNESS: Is there any evidence that</p> <p>24 the data in this table would be more reliable at six months</p> <p>25 than at the entire study period? No, not reliable. I mean</p>
<p>126</p> <p>1 all GEC members"?</p> <p>2 A. Right. Well, I think you have to go back up one or two</p> <p>3 phases. I think that where the doctor or the patient</p> <p>4 reported a possible complication they had to be adjudicated.</p> <p>5 The doctors didn't know what we were calling a complication.</p> <p>6 So the person might have had belly pain or they might have</p> <p>7 vomited up a little blood or they might have had a hemocult</p> <p>8 positive stool and they referred that patient in as a</p> <p>9 potential complication.</p> <p>10 At first screening a thousand of them were felt</p> <p>11 probably not to have it because they didn't have the data,</p> <p>12 and in fact they were -- almost all of them were thought to</p> <p>13 be negative events. So if the person, for example, had three</p> <p>14 hemocult stools and one was positive and two were negative</p> <p>15 and never needed a transfusion, never had black stools, never</p> <p>16 vomited blood, never had an endoscopy showing an ulcer, that</p> <p>17 was considered negative. But the 260 were the ones who were</p> <p>18 adjudicated by the whole committee and they were thought to</p> <p>19 be -- possibly be a complication, and then the next, the</p> <p>20 bottom one suggests that 35 were thought to be and 225 were</p> <p>21 thought to not be.</p> <p>22 Q. So what does GEC stand for?</p> <p>23 A. The Gastrointestinal Events Committee.</p> <p>24 Q. So did the box that I showed you indicate that the GEC</p> <p>25 reviewed the cases of 260 patients?</p>	<p>128</p> <p>1 the data should be the data.</p> <p>2 Q. (BY MR. MONTGOMERY) All right. I'm done with Exhibit 66 for</p> <p>3 now but we're probably going to go back to it occasionally so</p> <p>4 you want to keep that one handy.</p> <p>5 A. Okay.</p> <p>6 MR. BUSHOFSKY: It's quarter after.</p> <p>7 Q. (BY MR. MONTGOMERY) Do you recall after the CLASS study was</p> <p>8 complete when you first saw the results?</p> <p>9 A. You know, I don't.</p> <p>10 Q. Do you recall how, in what form you first saw the results?</p> <p>11 A. No.</p> <p>12 Q. Was there a big meeting that you can recall where you</p> <p>13 discussed the results for the first time?</p> <p>14 A. Well, there was a meeting that I could not attend and I don't</p> <p>15 know if that qualifies -- no, there was not a big meeting</p> <p>16 where we saw the results for the first time. I think I heard</p> <p>17 about them prior to that. But there was a meeting of the</p> <p>18 whole group and, you know, your division into the three</p> <p>19 different committees pursuant to that final report is fine,</p> <p>20 but it really was a bunch of consultants who were committed</p> <p>21 to putting a lot of work into making the study work. And</p> <p>22 there was a meeting I could not attend so I missed it, in</p> <p>23 which the data was considered for a whole day and I did not</p> <p>24 attend that meeting, but the answer to your question about</p> <p>25 whether there was a meeting in which the data was, here it</p>



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<p>129</p> <p>1 is, I don't remember. I don't think there was.</p> <p>2 Q. I'm going to show you what's previously been marked as</p> <p>3 Exhibit 65. Have you ever seen Exhibit 65 before?</p> <p>4 A. I don't think so.</p> <p>5 Q. Okay. Do you see on the bottom right-hand corner of the</p> <p>6 first slide it says March 20th, 2000?</p> <p>7 A. The right hand of the first slide.</p> <p>8 Q. The slide, not the page.</p> <p>9 A. Oh, I'm sorry. Yes.</p> <p>10 Q. Okay. And do you recall -- you can look at it on the top of</p> <p>11 your pile there, the study date, according to the final</p> <p>12 report, ended March 17, 2000?</p> <p>13 A. Okay.</p> <p>14 Q. All right. I'd like you to look at the third page of</p> <p>15 Exhibit 65, Bates number ending 864.</p> <p>16 A. Okay.</p> <p>17 Q. Do you see the slide says "Dissemination of CLASS data"?</p> <p>18 A. I do.</p> <p>19 Q. And under Consultants, were you a consultant?</p> <p>20 A. I was.</p> <p>21 Q. All right. And do you see it says "Subgroup by March 31st,</p> <p>22 committee chairs by April 6th"?</p> <p>23 A. I see it.</p> <p>24 Q. Okay. Does that sound about right to you of when you would</p> <p>25 have received the results of the CLASS study?</p>	<p>131</p> <p>1 Q. At what point?</p> <p>2 A. The point at which I went to the ACP.</p> <p>3 Q. Oh, yes, I understand that. I'm talking about the date of</p> <p>4 this document where --</p> <p>5 A. So what was the date that we decided when I had heard that --</p> <p>6 we all heard the results of the trial?</p> <p>7 Q. Let's take a look. It's three pages back. Bates number</p> <p>8 ending 864 of Exhibit 65.</p> <p>9 A. Yes.</p> <p>10 Q. And you see it says, "Consultants, subgroup by 3/31,</p> <p>11 committee chairs by 4/6"?</p> <p>12 A. Yes.</p> <p>13 Q. All right. So this document which is dated March 28th,</p> <p>14 2000 --</p> <p>15 A. Right.</p> <p>16 Q. -- that's before you had the results of the CLASS study,</p> <p>17 correct?</p> <p>18 MR. WEISS: Object to the form of the</p> <p>19 question.</p> <p>20 THE WITNESS: No, I'm not sure that's</p> <p>21 correct because I -- I don't remember when I got the results</p> <p>22 and it may have been prior to what's listed on this 864</p> <p>23 slide. I don't know that that's what happened. They may say</p> <p>24 it here but it doesn't mean that's what happened. This is a</p> <p>25 slide and I don't remember exactly when I heard about it. I</p>
<p>130</p> <p>1 A. Yes.</p> <p>2 Q. So it's on or about those days?</p> <p>3 A. I think so.</p> <p>4 Q. Okay. And did you make a presentation of the CLASS results</p> <p>5 to the American College of Physicians?</p> <p>6 A. I did.</p> <p>7 Q. Is that also spelled the ACP?</p> <p>8 A. Yes, it is.</p> <p>9 Q. Would you turn to the sixth page of Exhibit 65, 867.</p> <p>10 A. The sixth page. I'm sorry. I'm lost. Oh, 867, yes.</p> <p>11 Q. Do you see the slide there, it says Presentation Strategy?</p> <p>12 First entry says "ACP, Fred Silverstein, six-month efficacy</p> <p>13 and safety"?</p> <p>14 A. I do.</p> <p>15 Q. So does this indicate to you that the company had already</p> <p>16 decided that you were going to present six months of the</p> <p>17 CLASS data at ACP before you had even seen the results?</p> <p>18 MR. WEISS: Object to the form of the</p> <p>19 question.</p> <p>20 THE WITNESS: No.</p> <p>21 Q. (BY MR. MONTGOMERY) Why is that?</p> <p>22 A. Because I don't think that's what happened. I mean they may</p> <p>23 have said that they wanted me to present the six months of</p> <p>24 the data to the ACP, but I think at that point I already had</p> <p>25 the data.</p>	<p>132</p> <p>1 suspect I heard about it before then. So I have never seen</p> <p>2 this before and therefore I don't know exactly what this is.</p> <p>3 Q. (BY MR. MONTGOMERY) All right. Would you turn to page Bates</p> <p>4 number ending 884 of Exhibit 65.</p> <p>5 A. Okay.</p> <p>6 Q. Do you see this slide says, "GI symptoms are a risk factor</p> <p>7 for a GI event"?</p> <p>8 A. Yes.</p> <p>9 Q. And then you see the relative risk numbers underneath that?</p> <p>10 A. I do.</p> <p>11 Q. Do you remember ever seeing this analysis before?</p> <p>12 A. No, I don't specifically remember seeing this. It's</p> <p>13 interesting but I don't specifically remember seeing it.</p> <p>14 Q. All right.</p> <p>15 A. I don't remember.</p> <p>16 Q. You're not an expert statistician, correct?</p> <p>17 A. Correct.</p> <p>18 Q. But you are an expert with regard to gastrointestinal --</p> <p>19 A. I am.</p> <p>20 Q. -- issues, correct? Okay. Can you explain to me under the</p> <p>21 relative risk -- well, let's start with the first one, the</p> <p>22 NSAIDS it says 5.5. Do you know what that represents?</p> <p>23 A. You know, I'm not going to give you a definition of relative</p> <p>24 risk because I'm not sure I know it.</p> <p>25 Q. Okay.</p>



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<p style="text-align: right;">133</p> <p>1 A. Perhaps I should know it but at this point in my life I'm not 2 sure I can tell you exactly what a relative risk means 3 significantly. It's obvious an increase in risk. 4 Q. Yeah, let me ask it that way then, skip the fancy statistical 5 analysis. 6 A. Okay. 7 Q. But for the NSAIDs it says 5.5, correct? 8 A. I think what it means is that there's a 5.5 times risk of a 9 GI event in patients with GI symptoms versus patients without 10 GI symptoms on NSAIDs. 11 Q. On NSAIDs. And then the celecoxib or Celebrex it's 2.4, 12 right? 13 A. Correct. 14 Q. As a -- and the numbers for diclofenac are different from the 15 numbers for ibuprofen; is that correct? 16 A. Correct. 17 Q. Now, as a gastroenterologist do you know of any reason to 18 believe that the risk of a GI event in somebody with GI 19 symptoms should be higher in diclofenac as opposed to 20 ibuprofen? 21 A. Yes, and the reason is that diclofenac is more injurious than 22 ibuprofen is. And so, for example, if you were to say that 23 people who take NSAIDs can develop symptoms partially because 24 of a motility abnormality and/or a cerebral effect which I 25 mentioned, in two percent of people, in three percent of</p>	<p style="text-align: right;">135</p> <p>1 you've got a very high risk of developing significant -- of a 2 GI event on diclofenac much more than ibuprofen. So 3 therefore it's more of a predictor on diclofenac than it is 4 on ibuprofen. I'm sorry; that's as best I can do. I don't 5 know if that answered your question exactly. If not, ask it 6 again. 7 Q. Let me ask it a different way. All right. 8 We have -- pursuant to this slide, the relative risk 9 for the NSAIDs combined is 5.5, correct? 10 A. Right. 11 Q. And then the relative risk for diclofenac is 10.1, correct? 12 A. Right. 13 Q. Ibuprofen is 3.4, right? 14 A. Right. 15 Q. All right. If you personally were going to try and look at 16 this informative censoring theory and investigate the 17 association between symptoms and ulcer complications, which 18 of those numbers would you use? 19 MR. WEISS: Object to the form of the 20 question. 21 THE WITNESS: Well, it's most clear for 22 diclofenac. I mean what you can say is if patients who have 23 moderate symptoms of diclofenac are really at risk of 24 developing an adverse GI event more so than ibuprofen. 25 That's what I would say, and more so than celecoxib.</p>
<p style="text-align: right;">134</p> <p>1 people, but that in diclofenac the seven percent more who get 2 it from real irritation of the stomach or duodenum then you 3 could say that diclofenac has got the moderately severe GI 4 symptoms caused both by motility and by inflammation, 5 ibuprofen is just the motility. 6 So in other words, I don't think you can say -- it's 7 clearly because diclofenac is more injurious but -- I have to 8 go back to your question again. I lost myself a little bit. 9 Q. Sure. We're talking about the association between GI 10 symptoms and ulcer complications. 11 A. Yes, what I'm saying is GI symptoms are not the same 12 necessarily; that if somebody is complaining, My stomach is 13 gurgling and I feel an unease in my stomach, it's not as 14 severe as somebody saying, I've got a burrowing pain right 15 here in my epigastrium, or, The top of my stomach is killing 16 me. So I'm saying that I think that it means that diclofenac 17 is more injurious and more likely to cause a GI event than 18 ibuprofen is, which is what the common knowledge was going 19 into this trial. 20 Q. Right. I understand that diclofenac is more likely to cause 21 a GI event but is diclofenac -- are patients -- I'm sorry. 22 Are GI symptoms a better predictor of ulcer complications on 23 patients with -- taking diclofenac? 24 A. Well, I don't know if I can answer it from this slide. This 25 is saying that if you have moderate to severe GI symptoms</p>	<p style="text-align: right;">136</p> <p>1 MR. MONTGOMERY: Okay. What's our time? 2 MS. McPHEE: About 12:30. 3 MR. MONTGOMERY: All right. Let's go off 4 the record, please. 5 THE VIDEOGRAPHER: We are going off the 6 record. The time is 12:29 p.m. 7 (Recess 12:29-1:21.) 8 THE VIDEOGRAPHER: Okay. We are back on 9 the record. The time is 1:21 p.m. 10 11 EXAMINATION (Continuing) 12 BY MR. MONTGOMERY: 13 Q. You understand you're still under oath? 14 A. I do. 15 Q. All right. Going back to informative censoring theory that 16 we were talking about earlier. Is it your understanding that 17 GI symptoms are predictive of ulcer complications? 18 MR. BUSHOFSKY: Object to the form. 19 THE WITNESS: No, not if -- you're asking 20 me if I feel that way? 21 Q. (BY MR. MONTGOMERY) Yeah. 22 A. Not really because -- let's go over it again, at least in my 23 head. 24 100 patients, 50 of them have GI symptoms, 50 don't. 25 One person is going to get -- or two people are going to get</p>



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<p style="text-align: right;">137</p> <p>1 a complication. It's more likely to occur in the group of</p> <p>2 symptoms but most of the people with symptoms aren't going to</p> <p>3 get a complication. So that's why it throws everybody off,</p> <p>4 that's why -- but again, looking at it the other way, if</p> <p>5 you've had a complication odds are you did have symptoms. So</p> <p>6 you could say if you eliminated everybody with symptoms you</p> <p>7 should be eliminating or reducing the number of complications</p> <p>8 that occur.</p> <p>9 Q. All right. Let me ask it a different way then.</p> <p>10 Pursuant to informative censoring as you understand it,</p> <p>11 the CLASS results for ulcer complications became more biased</p> <p>12 as the trial went on; is that fair to say?</p> <p>13 MR. WEISS: Object to the form of the</p> <p>14 question.</p> <p>15 THE WITNESS: Yes.</p> <p>16 Q. (BY MR. MONTGOMERY) Okay. Is the same thing true with regard</p> <p>17 to symptomatic ulcers?</p> <p>18 MR. WEISS: Object to the form of the</p> <p>19 question.</p> <p>20 THE WITNESS: You have to rephrase that.</p> <p>21 I don't understand the question.</p> <p>22 Q. (BY MR. MONTGOMERY) Sure. Did the -- as the CLASS trial went</p> <p>23 on did informative censoring render the results biased --</p> <p>24 sorry. Let me do it again. Strike that.</p> <p>25 As the CLASS study progressed, did it become more and</p>	<p style="text-align: right;">139</p> <p>1 A. I saw it recently. I have never seen this until recently.</p> <p>2 Q. Okay.</p> <p>3 A. To my knowledge. Again, it was 10 years ago but I don't</p> <p>4 remember seeing it.</p> <p>5 Q. Fair enough. Can you turn to the second page of Exhibit 67,</p> <p>6 please.</p> <p>7 A. (Witness complies.)</p> <p>8 Q. The third paragraph that starts, "The study," do you see</p> <p>9 that?</p> <p>10 A. Uh-huh.</p> <p>11 Q. I'm going to read that sentence into the record. It says,</p> <p>12 "The study funded by Searle and Pfizer, Inc. found that</p> <p>13 Celebrex patients experienced significantly fewer GI ulcers</p> <p>14 and ulcer complications compared with ibuprofen or</p> <p>15 diclofenac."</p> <p>16 A. No, you forgot the word "symptomatic."</p> <p>17 Q. Oh, I did? I'm sorry.</p> <p>18 A. Unless you're reading a different sentence than I am.</p> <p>19 Q. No, I must have just missed it. Let me try it again.</p> <p>20 A. Yes.</p> <p>21 Q. "The study funded by Searle and Pfizer, Inc. found that</p> <p>22 Celebrex patients experienced significantly fewer symptomatic</p> <p>23 GI ulcers and ulcer complications compared with ibuprofen or</p> <p>24 diclofenac."</p> <p>25 Do you see that?</p>
<p style="text-align: right;">138</p> <p>1 more biased with regard to symptomatic ulcers as a result of</p> <p>2 informative censoring?</p> <p>3 MR. WEISS: Object to the form of the</p> <p>4 question.</p> <p>5 THE WITNESS: Well, I think if -- the</p> <p>6 question then is, if you have -- I'd say if you have an ulcer</p> <p>7 complication there's a good chance that you had symptoms</p> <p>8 before. The question is if you have a symptomatic ulcer was</p> <p>9 there a good chance you had symptoms before you developed a</p> <p>10 symptomatic ulcer, and that's a little bit more difficult for</p> <p>11 me to define. I don't know if I can say that. It's almost,</p> <p>12 you know, symptoms to predict symptoms and that's why it's</p> <p>13 not quite as clear to me.</p> <p>14 MR. MONTGOMERY: At this point I'd like</p> <p>15 to show the witness what's previously been marked as</p> <p>16 Exhibit 67.</p> <p>17 THE WITNESS: Okay.</p> <p>18 Q. (BY MR. MONTGOMERY) Is Exhibit 67 an April 17th, 2000 press</p> <p>19 release?</p> <p>20 A. It looks like it, yes.</p> <p>21 Q. Have you ever seen it before?</p> <p>22 A. I have seen it before.</p> <p>23 Q. Did you see it before it was issued?</p> <p>24 A. I did not.</p> <p>25 Q. So you saw it afterwards?</p>	<p style="text-align: right;">140</p> <p>1 A. I do.</p> <p>2 Q. And is it accurate to say that they experienced fewer</p> <p>3 symptomatic or complicated ulcers than ibuprofen or</p> <p>4 diclofenac?</p> <p>5 A. Let's see what this sentence says. Compared with ibuprofen</p> <p>6 or diclofenac. So there were no circumstances in which the</p> <p>7 patients were on both so "and/or" would be inappropriate. So</p> <p>8 I'm just trying -- maybe it's okay. I mean I can see the</p> <p>9 question -- but the study found there were fewer GI</p> <p>10 symptomatic ulcers and also complications compared with</p> <p>11 patients on ibuprofen or diclofenac. I guess the sentence</p> <p>12 reads okay to me. That reads okay.</p> <p>13 Q. All right. So would you agree with me that the --</p> <p>14 A. You know, it's patients who are on one or the other and then</p> <p>15 there were fewer. So I think that's reasonable.</p> <p>16 Q. There were not fewer symptomatic or complicated ulcers</p> <p>17 compared to diclofenac, correct?</p> <p>18 A. Now, are you referring back to what we looked at earlier?</p> <p>19 Q. Yes.</p> <p>20 A. Because I got a lot of stuff in my head.</p> <p>21 Q. Sure. You can look at the final report again too, if you</p> <p>22 want to refresh your memory.</p> <p>23 A. Now, and we're talking about which time period?</p> <p>24 Q. You mean the six-month or the entire study?</p> <p>25 A. No, the study. Found that patients experienced fewer</p>



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<p style="text-align: right;">141</p> <p>1 symptomatic GI ulcers and ulcer complications compared with 2 ibuprofen or diclofenac, and I guess this is talking about 3 six months, right? Because that's what the whole thing is 4 talking about? 5 Q. I don't know. Let's take a look at the first page of 6 Exhibit 67. Do you see the third paragraph there that says, 7 "The celecoxib long-term arthritis safety study at 8 approximately 13 months," et cetera? 9 A. Right. Okay. 10 Q. So does that lead you to believe that the press release is 11 talking about the 13th month data or the six-month data? 12 Take your time. You can read the whole thing if you want. 13 A. Yeah. Well, it would look like it's talking about 13-month 14 here because I don't see six months. Again, I did not see 15 this at the time and I have not had a chance to study it when 16 I saw it recently, I'm kind of aware of it. Let me just read 17 it a little bit. Matt, give me a second. 18 Q. Actually I'm going to ask you to read the entire thing. Read 19 the whole thing and then let me know when you're done. 20 A. Okay. (Witness complies.) Okay. 21 Q. All right. 22 A. So it looks to me as if it is talking about -- 23 Q. Let me ask a question first. 24 A. Okay. I'm sorry. 25 Q. Now you've had an opportunity to read the entirety of</p>	<p style="text-align: right;">143</p> <p>1 significant. 2 Q. Right. 3 A. Okay? 4 Q. Okay. Now, would you turn back to the press release. 5 A. Right. 6 Q. Let's look at the second page, Bates number ending 978. 7 A. Right. 8 Q. I'd like you to look at the sentence after the one that we 9 read before that says, "Celebrex was also associated with 10 numerically fewer ulcer complications than the NSAID 11 comparators among all patients and 64 percent fewer of these 12 serious events among nonaspirin users, a statistically 13 significant difference." 14 Do you see that? 15 A. I do. 16 Q. So that statement is only true as to the six-month data, not 17 the 13-month data, correct? 18 A. No, that -- before I agree to that I've got to look at this. 19 Q. Sure. Take your time. 20 A. (Witness reading.) 21 So numerically fewer than the comparators among all 22 patients. So they're not talking about -- they're talking 23 about all patients numerically. 24 Q. The focus of my question is really on the second part of that 25 sentence where it says, "64 percent fewer of the serious" --</p>
<p style="text-align: right;">142</p> <p>1 Exhibit 67, the April 17th, 2000 press release, correct? 2 A. Correct. 3 Q. And having done that, is it your understanding that this 4 press release is describing the six-month or 13-month results 5 of the CLASS study? 6 A. 13 months, to my read. 7 Q. Okay. All right. Do you have the final report handy? 8 A. Yes. 9 Q. All right. Would you please turn to page Bates number ending 10 117 of Exhibit 66, the final report? 11 A. Yes. 12 Q. All right. I'd like to direct you to the numbers that we 13 looked at earlier in Tables 1 and 2. 14 A. Yes. 15 Q. Do these indicate that at six months in patients not taking 16 aspirin there's a statistically significant difference 17 between Celebrex and the NSAIDs? 18 A. Correct. 19 Q. But at 12 months there is not a statistically significant 20 difference, correct? I'm sorry; of the entire study period 21 there's not a statistically significant difference, correct? 22 A. Well, we're doing categories within categories. So the first 23 one looks at the first six months, patients not taking 24 aspirin, it's significant. In the second one, the entire 25 study period, patients not taking aspirin it is not</p>	<p style="text-align: right;">144</p> <p>1 A. Okay. 2 Q. -- "events among nonaspirin users, a statistically 3 significant difference." 4 A. Okay. Hold on that. The first part of the sentence would 5 appear to be correct, "The numerically fewer ulcer 6 complications than the NSAID comparators among all patients," 7 so I think that is accurate. 8 Q. And to both the six-month and the entire data? 9 A. Yeah, by my reading. 10 Q. Okay. And then the second part of the sentence? 11 A. Then the second part of the sentence I'm looking at, 12 "64 percent fewer of these serious events among nonaspirin 13 users," so now we have to look at nonaspirin users. 14 So you want to know -- it is true at six months, the 15 question is it also true at 12 months. And what this thing 16 says is that Celebrex is .44, diclofenac is .48, and 17 ibuprofen is 1.14, right? 18 Q. I'm sorry. Oh, I see where you're pointing. 19 A. I'm trying to look at -- we agree that what they said is true 20 for the first six months; that is, in nonaspirin users there 21 is a statistically significant difference. That's the .037. 22 You asked whether that difference was also true at 12 months 23 or are they referring now to only six months? 24 Q. That's correct. 25 A. And what I'm saying is so .48 and .48 and 1.14 -- well, I</p>



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<p style="text-align: right;">145</p> <p>1 don't think it's accurate to say it was a statistically 2 significant difference at 12 -- in the whole data study 3 period, although if you combine diclofenac and ibuprofen it 4 was less. 5 Q. All right. So for the sentence that we were discussing from 6 the April 17th, 2000 press release, it can only be true if 7 you're talking about the six-month data, not the entire study 8 period; is that correct? 9 A. Well, "associated numerically fewer ulcer complications than 10 the NSAID comparators among all patients and 64 percent fewer 11 among nonaspirin users," nonaspirin users. 12 So it was a lot fewer in the nonaspirin users at six 13 months and it was fewer but not as big a difference in the 14 entire study period and didn't reach statistical 15 significance. So I -- the way I'm reading it, it doesn't 16 look like it's correct. 64 percent fewer of these serious 17 adverse events among nonaspirin users. So how many events 18 were there? So if you look at the patients not taking 19 aspirin, at the crude numbers, there were 18 patients on 20 celecoxib and -- let's see, 15 on -- or total nine, total of 21 nine versus a total of 13. So were they saying that 13 to 9 22 is a 65 percent drop? It's not that much. 23 So I would say, based on what I'm looking at right 24 here, it would be more accurate to say it was statistically 25 significant for the six months.</p>	<p style="text-align: right;">147</p> <p>1 THE WITNESS: To my knowledge that is 2 accurate if you're saying that compared with patients who are 3 on ibuprofen or diclofenac, a group of patients who are one 4 or the other. 5 Q. (BY MR. MONTGOMERY) And the way you're interpreting the 6 phrase "ibuprofen or diclofenac," would it change the meaning 7 of the sentence at all if we substituted "and" for "or"? So 8 if the sentence read "ibuprofen and diclofenac" would it 9 still be accurate? 10 MR. WEISS: Object to the form of the 11 question. 12 THE WITNESS: No, because it would 13 suggest that the patients were on ibuprofen and diclofenac, 14 whereas in fact they were on one or the other. I don't think 15 you can say "and." I mean I think the way to correct it to 16 make it super clear would be to add half of the sentence, 17 "compared with a group of patients who are either on 18 ibuprofen or diclofenac." So I don't think "and" would 19 clarify it. 20 Q. (BY MR. MONTGOMERY) But you're saying -- you think if it said 21 "and" instead of "or" it would actually be inaccurate then? 22 A. I think it could be misleading. 23 Q. All right. Let's look at the first page of Exhibit 67, the 24 April 17th, 2000 press release. 25 A. Well -- please finish your question.</p>
<p style="text-align: right;">146</p> <p>1 Q. Okay. So would you say that the statement -- let me read it 2 into the record again. It says, "64 percent fewer of these 3 serious events among nonaspirin users, a statistically 4 significant difference." 5 That's inaccurate? 6 MR. WEISS: Object to the form of the 7 question. 8 THE WITNESS: Yeah, they don't 9 specifically say whether it's six or 12 months. And without 10 that I think it's not -- it's not accurate compared to this. 11 Q. (BY MR. MONTGOMERY) Okay. Let's go back -- 12 A. Unless I'm misreading the data. I think it is true for the 13 patients in six months that is a statistically significant 14 reduction. Okay. 15 Q. Let's go to the sentence -- the first sentence in that 16 paragraph we were just looking at. You think that sentence 17 is accurate; is that correct? I'll read it again. "The 18 study funded by Searle and Pfizer, Inc. found that Celebrex 19 patients experienced significantly fewer symptomatic GI 20 ulcers and ulcer complications compared with ibuprofen or 21 diclofenac." 22 Do you see that one? 23 A. Yes. 24 Q. Okay. And your testimony is that that statement is accurate? 25 MR. BUSHOFSKY: Objection to form.</p>	<p style="text-align: right;">148</p> <p>1 Q. Sure. I'd like to direct you to the second full paragraph, 2 I'm going to read into the record. The first sentence in any 3 event. "Also, in comparison to Celebrex, ibuprofen and 4 diclofenac were associated with a significantly greater GI 5 blood loss." 6 I'm sorry; that's not the one I wanted to read. 7 Scratch that. 8 It's the first sentence of the press release. "In a 9 landmark study to assess the overall long-term safety of the 10 COX-2 specific inhibitor Celebrex (celecoxib capsules) 11 arthritis patients taking four times the recommended 12 osteoarthritis (OA) dose of the drug experienced fewer 13 symptomatic gastrointestinal (GI) ulcers and ulcer 14 complications than patients taking ibuprofen and diclofenac, 15 a difference that was statistically significant based on a 16 combined analysis of Celebrex versus these two traditional 17 nonsteroidal anti-inflammatory drugs (NSAIDs)." 18 Now, that sentence says ibuprofen "and" diclofenac, 19 correct? 20 A. That's correct; however, the part that follows it says "on a 21 combined analysis." 22 Q. Right. So it's your understanding that that sentence is 23 accurate then? 24 A. Yes. 25 Q. All right.</p>



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<p style="text-align: right;">149</p> <p>1 A. Although I'm not an English major.</p> <p>2 MR. MONTGOMERY: I'd like to ask the</p> <p>3 court reporter to mark what will be <u>Exhibit 198</u>.</p> <p>4 (Exhibit No. 198 marked</p> <p>5 for identification.)</p> <p>6 Q. (BY MR. MONTGOMERY) Feel free to look at the entire exhibit.</p> <p>7 I'm only going to ask you about the contents of the e-mail at</p> <p>8 the very bottom of the first page.</p> <p>9 A. Okay. (Witness complies.) Okay.</p> <p>10 Q. So this e-mail refers to a teleconference with yourself,</p> <p>11 Dr. Geis, Dr. Simon and Dr. Welton on April 17th, 2000; is</p> <p>12 that correct?</p> <p>13 A. That's what it says.</p> <p>14 Q. And did you participate in a teleconference on that date?</p> <p>15 A. I don't think so. Perhaps somebody here who's smarter than I</p> <p>16 am can figure it out but I don't think I did.</p> <p>17 MR. MONTGOMERY: I'd like to ask the</p> <p>18 court reporter to mark what will be <u>Exhibit 199</u>.</p> <p>19 (Exhibit No. 199 marked</p> <p>20 for identification.)</p> <p>21 Q. (BY MR. MONTGOMERY) For the record, <u>Exhibit 199</u> is an e-mail</p> <p>22 dated April 24th, 2000, that attaches an article from the</p> <p>23 pink sheet dated April 24th, 2000, Bates No. DEFS 00390944</p> <p>24 through 46.</p> <p>25 Have you read all of <u>Exhibit 199</u> now?</p>	<p style="text-align: right;">151</p> <p>1 A. I do.</p> <p>2 Q. And do you believe that you said that?</p> <p>3 A. You know, it's not in quotes. You know, when Lee Simon is</p> <p>4 being quoted it's in quotes. If you look at the -- on the</p> <p>5 second page, 945, halfway down it says, "This data set,</p> <p>6 because it demonstrates the incidence of complications of</p> <p>7 bleeding perforation, obstruction, et cetera," is in quotes.</p> <p>8 What they said I said is not in quotes. Because that is not</p> <p>9 familiar to me. And it was, you know, albeit true that the</p> <p>10 six months patients were required to stay on for six months,</p> <p>11 but there were other reasons for the head-to-head comparison.</p> <p>12 So that's the best I can do. If they had quoted me, then,</p> <p>13 you know, assuming they were accurate then it's what I said,</p> <p>14 but I don't remember this. It does hit some of the cogent</p> <p>15 points, though.</p> <p>16 Q. All right. So you don't believe you said what the article</p> <p>17 attributes to you?</p> <p>18 A. You know, I don't remember.</p> <p>19 Q. Okay. You don't remember one way or the other?</p> <p>20 A. Correct.</p> <p>21 Q. Let me ask you then: Separate from the quote, were data from</p> <p>22 the first six months of the trial used because patients were</p> <p>23 not required to remain on their assigned drug after six</p> <p>24 months?</p> <p>25 A. Ask that one again.</p>
<p style="text-align: right;">150</p> <p>1 A. I have.</p> <p>2 Q. Okay. Are you familiar with the pink sheet?</p> <p>3 A. No. I -- kind of vaguely, but I guess it's a fax sheet about</p> <p>4 the pharmaceutical industry is all I know about it.</p> <p>5 Q. Okay. Having read this article does it refresh your</p> <p>6 recollection at all about participating in a conference call?</p> <p>7 A. No.</p> <p>8 Q. Okay. Do you see in the first paragraph of the story it</p> <p>9 refers to a CLASS 13-month trial?</p> <p>10 A. I do.</p> <p>11 Q. And then in the second paragraph do you see the reference to</p> <p>12 an April 17th conference call?</p> <p>13 A. Yes.</p> <p>14 Q. Now I'd like to direct you to the paragraph at the bottom of</p> <p>15 the page, near the bottom of the page that starts, "Data from</p> <p>16 the first six months of the trial."</p> <p>17 Do you see that?</p> <p>18 A. Yes, yeah.</p> <p>19 Q. I'm going to read that into the record. It says, "Data from</p> <p>20 the first six months of the trial were used for the</p> <p>21 head-to-head comparison of NSAIDs because patients were not</p> <p>22 required to remain on their assigned drug after the six</p> <p>23 months, study investigator Fred Silverstein, M.D., University</p> <p>24 of Washington explained."</p> <p>25 Do you see that?</p>	<p style="text-align: right;">152</p> <p>1 Q. All right. You're familiar with the six-month data analysis</p> <p>2 of the CLASS study?</p> <p>3 A. Yes.</p> <p>4 Q. Was one of the reasons for that six-month analysis because</p> <p>5 patients were only required to be on the drug for six months?</p> <p>6 MR. WEISS: Object to the form of the</p> <p>7 question.</p> <p>8 THE WITNESS: Yes, but it was not one of</p> <p>9 the overwhelming reasons. And I just want to make one point.</p> <p>10 If you look at the paragraph that starts at the very bottom</p> <p>11 of that first page, "While the incidence of complications</p> <p>12 were cut in half, the rate of serious ulcer complications was</p> <p>13 the primary end point of the study. 'The issue here is you</p> <p>14 are dealing with relatively small numbers of people so it did</p> <p>15 not reach a significant level of .05.'"</p> <p>16 And that's in quotes. So -- and that I would say,</p> <p>17 that's the kind of thing I would say. So I don't know why</p> <p>18 they didn't put it in quotes and I don't know if they were</p> <p>19 accurate on that earlier paragraph.</p> <p>20 Q. (BY MR. MONTGOMERY) All right. My question, though, is:</p> <p>21 Regardless of whether you said it or not, is that statement</p> <p>22 accurate that the first six months of the trial were used for</p> <p>23 the head-to-head comparison because patients were not</p> <p>24 required to remain on their assigned drug after six months?</p> <p>25 MR. WEISS: Objection; asked and</p>



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<p>153</p> <p>1 answered.</p> <p>2 THE WITNESS: You know I would say no, it</p> <p>3 would be more complete if we talked about other things that</p> <p>4 happened.</p> <p>5 Q. (BY MR. MONTGOMERY) Such as?</p> <p>6 A. Such as informative censoring.</p> <p>7 THE VIDEOGRAPHER: Counsel, there's about</p> <p>8 five minutes left on the tape.</p> <p>9 Q. (BY MR. MONTGOMERY) Without including a discussion of</p> <p>10 informative censoring, could that statement on its own</p> <p>11 potentially mislead the reader?</p> <p>12 MR. WEISS: Object to the form of the</p> <p>13 question.</p> <p>14 THE WITNESS: I don't know.</p> <p>15 Q. (BY MR. MONTGOMERY) Informative censoring was a more</p> <p>16 important reason to use the six-month analysis compared to</p> <p>17 the minimum exposure; isn't that right?</p> <p>18 MR. WEISS: Object to the form of the</p> <p>19 question.</p> <p>20 THE WITNESS: Well, I would say it was</p> <p>21 equally, equally important or more important.</p> <p>22 Q. (BY MR. MONTGOMERY) But at least according to this it wasn't</p> <p>23 mentioned; is that right?</p> <p>24 A. Not that I see.</p> <p>25 MR. MONTGOMERY: All right. Let's go off</p>	<p>155</p> <p>1 conference call?</p> <p>2 Q. Oh, in the second paragraph it says --</p> <p>3 A. Okay. Okay.</p> <p>4 Q. All right. So --</p> <p>5 A. Yes, I guess that --</p> <p>6 Q. Let me ask the question again then.</p> <p>7 A. Right.</p> <p>8 Q. Do you understand this to be another article in part about an</p> <p>9 April 17, 2000 conference call?</p> <p>10 A. Yes.</p> <p>11 Q. All right. Do you see the seventh paragraph down that starts</p> <p>12 "Data"?</p> <p>13 A. Yes.</p> <p>14 Q. All right. I'll read this into the record. "Data from the</p> <p>15 first six months of the trial were considered to be the most</p> <p>16 consistent because patients were not required to remain on</p> <p>17 their assigned drugs after the six-month period, Fred</p> <p>18 Silverstein, M.D., University of Washington explained."</p> <p>19 Do you see that?</p> <p>20 A. I do.</p> <p>21 Q. And do you remember making that statement on a conference</p> <p>22 call?</p> <p>23 A. No, I do not. And once again, I would point out that in the</p> <p>24 first and the second and third, at least the second paragraph</p> <p>25 they're using quotes, and they're not using quotes around</p>
<p>154</p> <p>1 the record.</p> <p>2 THE VIDEOGRAPHER: We are going off the</p> <p>3 record. The time is 1:55 p.m.</p> <p>4 (Recess 1:55-2:05.)</p> <p>5 THE VIDEOGRAPHER: Okay. We are back on</p> <p>6 the record. The time is 2:05 p.m. This is the beginning of</p> <p>7 Tape No. 4.</p> <p>8</p> <p>9 EXAMINATION (Continuing)</p> <p>10 BY MR. MONTGOMERY:</p> <p>11 Q. You understand you're still under oath?</p> <p>12 A. Yes.</p> <p>13 MR. MONTGOMERY: I'd like to ask the</p> <p>14 court reporter to mark what will be Exhibit 200.</p> <p>15 (Exhibit No. 200 marked</p> <p>16 for identification.)</p> <p>17 Q. (BY MR. MONTGOMERY) Take your time and read it and let me</p> <p>18 know when you're done. For the record, Exhibit 200 is an</p> <p>19 April 18th, 2000 e-mail from Mona Wahba attaching an</p> <p>20 April 18th, 2000 article from Health News Daily.</p> <p>21 A. (Witness complies.) Okay.</p> <p>22 Q. Does this appear to be another news article about an</p> <p>23 April 17th, 2000 conference call?</p> <p>24 A. Well, how can you say that? I don't understand. Tuesday,</p> <p>25 April 18th. I'm sorry; where do you see that this was the</p>	<p>156</p> <p>1 this. It's virtually the same paragraph that's in the other</p> <p>2 news article.</p> <p>3 Q. And you still don't remember --</p> <p>4 A. I don't.</p> <p>5 Q. Let me finish the question. Sorry.</p> <p>6 You still don't remember participating in a conference</p> <p>7 call on or about these dates; is that right?</p> <p>8 A. I do not clearly remember, no.</p> <p>9 Q. Okay. All right. Do you recall the JAMA article we talked</p> <p>10 about earlier?</p> <p>11 A. The -- yes.</p> <p>12 Q. You were an author of that article, correct?</p> <p>13 A. Correct.</p> <p>14 Q. Did you write the first draft?</p> <p>15 A. No.</p> <p>16 Q. Do you know who did?</p> <p>17 A. I think Dr. Lefkowitz did, but I'm not sure.</p> <p>18 Q. At some point, though, you received a draft?</p> <p>19 A. I did.</p> <p>20 Q. Okay. And then did you make comments and provide those to</p> <p>21 someone?</p> <p>22 A. I did.</p> <p>23 Q. And to whom did you provide them?</p> <p>24 A. Dr. Lefkowitz.</p> <p>25 Q. And was he in charge of incorporating or not incorporating</p>



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<p style="text-align: right;">157</p> <p>1 your comments?</p> <p>2 A. He was.</p> <p>3 Q. Do you recall any suggestions or comments that you made that</p> <p>4 he did not incorporate?</p> <p>5 A. I do.</p> <p>6 Q. What were they?</p> <p>7 A. I thought that the article needed a section that dealt with</p> <p>8 this issue about why we included six months and not the</p> <p>9 entire data set.</p> <p>10 Q. So you wanted a section discussing informative censoring and</p> <p>11 the justification for the six-month analysis?</p> <p>12 A. Correct.</p> <p>13 Q. And was that suggestion adhered to?</p> <p>14 A. No.</p> <p>15 Q. And why not?</p> <p>16 A. I don't know. I -- we discussed it several times, but I</p> <p>17 remember very clearly telling Dr. Geis that we had to get a</p> <p>18 section in to the paper to explain why we were presenting the</p> <p>19 six months of data and not the 12 months. And I think we</p> <p>20 talked about it twice and I think the second time, or at</p> <p>21 least in one of the conversations, the last one we had prior</p> <p>22 to publication he said absolutely he told Lefkowitz to get</p> <p>23 the section and it was going to be done.</p> <p>24 Q. But it wasn't?</p> <p>25 A. Correct.</p>	<p style="text-align: right;">159</p> <p>1 censoring is part of that and I felt that was logical to</p> <p>2 pursue that. I mean it was logical to have that be the main</p> <p>3 thrust of the paper, but I thought that it was reasonable to</p> <p>4 let the reader know that the trial -- you know, as in these</p> <p>5 news articles where it's stated very clearly that it was a</p> <p>6 13-month trial, I thought it would have been reasonable to</p> <p>7 put a section in to that effect.</p> <p>8 Q. And why did you think it would be reasonable to do that?</p> <p>9 A. I thought it would be important to let the reader know that</p> <p>10 this was the first six months of a trial that went on a</p> <p>11 couple of months longer.</p> <p>12 I would like to add something to that. May I?</p> <p>13 Q. Yes, you may.</p> <p>14 A. In addition, what I was told, and this is a situation where,</p> <p>15 you know, I am not a full-time employee of Searle or Pfizer,</p> <p>16 I'm a consultant, and I was told that the six-month missed</p> <p>17 the primary end point and so did the full data set, no</p> <p>18 difference there. I was told that there were no difference</p> <p>19 in serious adverse events from the standpoint of</p> <p>20 cardiovascular, cerebral vascular, renal hypertensive, any of</p> <p>21 those events. So there was not a reason to -- it wasn't as</p> <p>22 if things were happening after six months that were not</p> <p>23 happening before six months and therefore we had to say it</p> <p>24 because otherwise you're not letting the reader know about</p> <p>25 something that was very important that was happening after</p>
<p style="text-align: right;">158</p> <p>1 Q. And did you sign off on the JAMA article without that section</p> <p>2 before publication?</p> <p>3 A. Well, it's hard to say because when you say "sign off" it</p> <p>4 sounds as if I approved of it and in fact what I said was the</p> <p>5 article is fine but I want this other section included.</p> <p>6 That's what happened. It was not a question of my saying,</p> <p>7 Oh, yes, this is fine the way it is.</p> <p>8 Q. Right. I guess let me ask it a different way.</p> <p>9 Did you approve -- communicate your approval of the</p> <p>10 JAMA article to anyone at Pharmacia based on the version that</p> <p>11 was ultimately printed in JAMA?</p> <p>12 MR. WEISS: Object to the form of the</p> <p>13 question.</p> <p>14 THE WITNESS: Yeah, hard to answer. I</p> <p>15 would probably say no because I thought it was going to have</p> <p>16 another section added to it. Otherwise I thought it was</p> <p>17 fine.</p> <p>18 Q. (BY MR. MONTGOMERY) And why did you think that it should have</p> <p>19 a section concerning the six-month analysis and the</p> <p>20 justifications therefor?</p> <p>21 A. Well, it seemed to me that the six-month analysis was clear.</p> <p>22 It corresponded to other studies that had been done like the</p> <p>23 mucosa trial. It did not suffer from something weird that</p> <p>24 was happening to the diclofenac and ibuprofen patients. It</p> <p>25 was more readily understood so I felt -- and informative</p>	<p style="text-align: right;">160</p> <p>1 six months than before six months.</p> <p>2 And several times I asked Dr. Geis, Were there any</p> <p>3 adverse events that were apparent after six months that were</p> <p>4 not apparent in the first six months? And he said -- every</p> <p>5 time I asked him he said no. So I felt that it was okay to</p> <p>6 look at the six months of data but I did feel that it would</p> <p>7 be more complete to let the reader know that there was more</p> <p>8 data and that -- and why it was not included.</p> <p>9 Q. When you say that you asked whether there were any adverse</p> <p>10 events after six months, do you mean that there were adverse</p> <p>11 events single after six months that didn't exist or that</p> <p>12 there were literally no adverse events that happened after</p> <p>13 the six-month period?</p> <p>14 A. Right, I'm not talking about serious adverse GI events, I'm</p> <p>15 talking about other events. So, for example, if at seven</p> <p>16 months there were, you know, a series of patients who had</p> <p>17 strokes or had myocardial infarctions, then, you know, you</p> <p>18 can't -- how can you not present that data? That would be</p> <p>19 essential to present.</p> <p>20 What I was told was that was not the case. There were</p> <p>21 no signals that there were cardiovascular, cerebral vascular,</p> <p>22 renal vascular events in the six to whatever that weren't</p> <p>23 already reported in the zero to six.</p> <p>24 Q. And is it your understanding that that's true?</p> <p>25 A. Yes.</p>



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<p>161</p> <p>1 Q. Notwithstanding that, do you still think that the JAMA 2 article should have included a section explaining the reasons 3 for the six-month analysis? 4 A. Yes. 5 Q. Were you concerned that the reader might, "a" reader of the 6 JAMA article might be misled if they read a description of 7 the six-month results without knowing what the 13-month 8 results were or why the six months had been presented? 9 MR. WEISS: Object to the form of the 10 question. 11 Q. (BY MR. MONTGOMERY) Let me ask it again. 12 A. Yeah. 13 Q. I'm going to ask it differently. 14 A. Yeah. 15 Q. Were you concerned that without the section that you wanted 16 put in that -- concerning informative censoring, that a 17 reader of the JAMA article might be misled? 18 MR. WEISS: Object to the form of the 19 question. 20 THE WITNESS: I would have to answer yes 21 and no. No, because I think that what the first six months 22 showed was consistent with all the other data we had and 23 showed that Celebrex and paradox with data that's been 24 published since then, but that showed that Celebrex is less 25 injurious to the GI tract than the other two comparator</p>	<p>163</p> <p>1 either. 2 Q. What about secondary end points? If one secondary end point 3 is statistically significant at six months but not 12 months, 4 would that change your perspective? 5 MR. WEISS: Object to the form of the 6 question. 7 THE WITNESS: I would have to know what 8 kind of secondary end point that was because what I was told, 9 again, was that although -- you see, this gets back a little 10 bit to the conundrum of how to design a trial like this. The 11 decision was made not to include symptomatic ulcers. In the 12 Vioxx trial they did include symptomatic ulcers. Here they 13 didn't. So when Steve Geis told me about the data he said it 14 wasn't -- we didn't make significance for six months or for 15 the whole data set. 16 However, when you add symptomatic ulcers, we did make 17 significance for six months and the whole data set. And then 18 there was also this interesting correlation with aspirin 19 where we expected from previous trials that the rate of using 20 aspirin would be about 10 percent and in the CLASS trial it 21 turned out to be 22 percent. And the problem with aspirin is 22 that it inhibits both the COX-1 and COX-2 enzyme systems and 23 therefore kind of undo -- undoes the physiological benefit of 24 having a selective inhibitor. 25 Q. (BY MR. MONTGOMERY) All right. Just to be clear: So you --</p>
<p>162</p> <p>1 NSAIDs. So I would say no, I don't think the reader was 2 misread; however, I do think it should have been included. 3 Q. (BY MR. MONTGOMERY) So is it your understanding that 4 generally speaking the six-month results and the 13-month 5 results are the same? 6 A. I know that there are one or two differences but the answer 7 is yes, I think they are very close to each other and the 8 differences are -- relate back to the change in the baseline 9 population caused by informative censor. 10 Q. But if the results of the study are the same in six months 11 and the entire data set, why not just publish the entire data 12 set? 13 A. Because it wasn't that simple. The patients dropped off in 14 the other two groups so the question was what was happening, 15 and it wasn't clear to us what was happening. It's like 16 there's something going on, it's almost as if somebody -- I 17 don't know, it wasn't clear what was happening. So it was 18 clear for the first six months. It was not clear for the 19 period after that. But there was no fundamental difference 20 according to the way the data was presented to me. It was 21 not a question of -- you know, if it had been -- if the 22 primary end point had been statistically significant at six 23 months but not at 12 months, then I would have said, You 24 can't do that. You know, you got to present it both ways. 25 But what I was told was that it was not significant at</p>	<p>164</p> <p>1 it your position that a section should be included in the 2 JAMA article disclosing the reasons for the six-month 3 analysis? 4 A. Correct. 5 MR. WEISS: Object to the form of the 6 question. 7 THE WITNESS: Correct. 8 Q. (BY MR. MONTGOMERY) And you communicated those to Dr. Geis; 9 is that correct? 10 A. That's correct. 11 Q. And approximately how many times did you tell him that? 12 A. Well, I know it was -- we discussed it but I remember very 13 clearly one conversation when the paper was, you know, in the 14 final stages and I said, We've got to get that section in. 15 So that's the conversation I remember. And he said, 16 Absolutely, I've told JAMA it's going to go in. 17 Q. Was that a phone conversation or in person? 18 A. It was -- a phone. 19 Q. Was anybody else on the call? 20 A. I don't think so. 21 Q. Did you ever talk to any of the other authors of the JAMA 22 article regarding the inclusion of a section about 23 informative censoring and the six-month analysis? 24 A. No, but I did ask Dr. Geis -- remember I had told you I had 25 missed a meeting? And that was a meeting in which they had a</p>



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<p style="text-align: right;">165</p> <p>1 discussion for a whole day about how to present the data and</p> <p>2 the benefits of six months versus longer data, and I missed</p> <p>3 that. So I asked Dr. Geis, How -- how are Lee Simon and Bob</p> <p>4 Makuch and the other people about presenting the data in this</p> <p>5 form? And he said it was -- as I remember he said that was</p> <p>6 fine with them. They thought it was the way to go.</p> <p>7 Q. During the drafting process of the JAMA article when comments</p> <p>8 were being submitted, did you ever see the comments of any of</p> <p>9 the other authors?</p> <p>10 A. I don't remember. Because the corresponding author was</p> <p>11 Lefkowitz and he really was the pivot person with the paper.</p> <p>12 We all had input. We all knew what was going on. We all</p> <p>13 knew where the data was. It was all open amongst all the</p> <p>14 authors. So if Jim were alive, it's unfortunate that he died</p> <p>15 prematurely, but if he were alive, he would be the person who</p> <p>16 would have seen everybody's comments. It would not</p> <p>17 necessarily, and I don't believe they did come to me, even as</p> <p>18 first author.</p> <p>19 Q. Did Dr. Simon ever tell you that he thought the median</p> <p>20 exposure to the drugs should be included in the JAMA article?</p> <p>21 A. I don't remember. He's a very bright guy but I just don't</p> <p>22 remember that specific issue.</p> <p>23 Q. So as far as you knew when the JAMA article was submitted, it</p> <p>24 included the section that you suggested about informative</p> <p>25 censoring, correct?</p>	<p style="text-align: right;">167</p> <p>1 wasn't included in the final JAMA article, correct?</p> <p>2 A. That's correct.</p> <p>3 Q. And when did you discover that?</p> <p>4 A. When I saw the paper.</p> <p>5 Q. When it was published?</p> <p>6 A. That's correct.</p> <p>7 Q. And how did you feel when you saw that the section that you</p> <p>8 wanted was no longer -- was not included?</p> <p>9 A. I was not happy about it.</p> <p>10 Q. And did you talk to anybody about that?</p> <p>11 A. I did.</p> <p>12 Q. Who did you talk to?</p> <p>13 A. Dr. Geis.</p> <p>14 Q. And -- on the phone?</p> <p>15 A. On the phone.</p> <p>16 Q. And what did you say?</p> <p>17 A. Well, I asked him, What happened? I thought you said you</p> <p>18 were going to put in the section on what happened to the data</p> <p>19 after six months? And what I learned was that -- what I took</p> <p>20 away from the conversation was that the article went on a</p> <p>21 fast track because the JAMA -- the New England Journal had</p> <p>22 just published the Vioxx trial and it was implied that JAMA</p> <p>23 wanted to get the Celebrex trial out quickly and it sort of</p> <p>24 took a life of its own and went through and was published</p> <p>25 before this other section could be added to it; that one of</p>
<p style="text-align: right;">166</p> <p>1 MR. WEISS: Object to the form of the</p> <p>2 question.</p> <p>3 THE WITNESS: No.</p> <p>4 Q. (BY MR. MONTGOMERY) Let me put it a different way.</p> <p>5 A. Okay.</p> <p>6 Q. At the time the submission was made, you didn't actually see</p> <p>7 the final product, correct?</p> <p>8 MR. WEISS: Object to the form of the</p> <p>9 question.</p> <p>10 THE WITNESS: At the time the submission</p> <p>11 was made, well, I saw a product that was putatively a final</p> <p>12 product and I said, You've got to add a section to that, and</p> <p>13 I didn't see what happened after that. I was told it would</p> <p>14 be added and I didn't see that section added.</p> <p>15 Q. (BY MR. MONTGOMERY) Okay. So subsequent to that conversation</p> <p>16 the final manuscript was submitted to JAMA, correct?</p> <p>17 A. I don't know that. It may well have -- it probably had been</p> <p>18 submitted to JAMA. When you submit a manuscript it goes</p> <p>19 through a process of going to page proofs and comes back as a</p> <p>20 draft and page proofs, and it was somewhere in there that I</p> <p>21 saw it and said, Where is the section that we talked about</p> <p>22 adding on informative censoring? And Geis said, I talked to</p> <p>23 Steve, he's going to -- to Jim, he's going to be sure it's</p> <p>24 there.</p> <p>25 Q. Then at some point you discovered that the section in fact</p>	<p style="text-align: right;">168</p> <p>1 the editors at JAMA knew that there was more data that there</p> <p>2 was longer data, so JAMA was not unaware of that. And then</p> <p>3 the most compelling argument was, this is all in the hands of</p> <p>4 the FDA. It is all going to be aired -- you know, this is</p> <p>5 now we're talking about October of 2000. It is -- in two or</p> <p>6 three months this is going to be aired in front of hundreds</p> <p>7 of people and all the data is going to be discussed, the</p> <p>8 six-month data, the whole data set. Nothing has been hidden,</p> <p>9 it's all open at the FDA presentation which CNN and all these</p> <p>10 other networks come to.</p> <p>11 Q. Did you find that explanation satisfactory?</p> <p>12 A. That's a very -- calls for a very subjective response.</p> <p>13 Q. I'm asking for your subjective responses.</p> <p>14 A. Yeah. It was not the answer I wanted in the sense that I</p> <p>15 wanted to know that it actually was in the journal. It</p> <p>16 explained to some degree what happened and I guess I felt</p> <p>17 that the compelling part of it was that all the data was at</p> <p>18 the FDA, was all going to be aired in a whole day session and</p> <p>19 that nobody would feel that the data was obfuscated or</p> <p>20 important data was withheld, and therefore, I didn't insist</p> <p>21 that we do something about it.</p> <p>22 Q. Did you ever talk to Dr. Lefkowitz about it?</p> <p>23 A. I don't remember. I don't remember. Most of the contact I</p> <p>24 had from that time was with Geis.</p> <p>25 Q. After the publication of the JAMA article did you ever talk</p>



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<p style="text-align: right;">169</p> <p>1 to any of the other -- any of your other co-authors about the</p> <p>2 omission of the section you wanted regarding informative</p> <p>3 censoring?</p> <p>4 A. Not that I remember.</p> <p>5 Q. Did you believe Dr. Geis's representation to you that the</p> <p>6 publication of the article was so short tracked that there</p> <p>7 was no way to get in the section that you wanted before</p> <p>8 publication?</p> <p>9 MR. WEISS: Object to the form of the</p> <p>10 question, mischaracterizes the witness's testimony.</p> <p>11 THE WITNESS: To answer that, I have to</p> <p>12 do a little short diversion and it won't be a long</p> <p>13 digression. If you were -- if you were doing these studies,</p> <p>14 the amount of data would fill this room. The thought that</p> <p>15 any one person, me or anybody else who's doing this on a</p> <p>16 consulting basis which means I've got another job, can verify</p> <p>17 every piece of information is just not reality, is not what</p> <p>18 happens. It will never be what happens. You have to trust</p> <p>19 the people you work with and if you don't you shouldn't work</p> <p>20 with them. You should never be in a situation where you</p> <p>21 don't trust somebody and you continue working with them.</p> <p>22 So I had experience of working with Steve Geis going</p> <p>23 back to about 1983 when I first went to the FDA when that guy</p> <p>24 Andre Robert was talking about Misoprostol and trying to get</p> <p>25 Misoprostol approved. I think it was 1984 or something like</p>	<p style="text-align: right;">171</p> <p>1 was discussed as -- pretty much as completely as you can</p> <p>2 discuss it at that FDA regulatory meeting in February of</p> <p>3 2001, and everybody in the back of the room -- and the whole</p> <p>4 room was filled because everybody's there, all the companies</p> <p>5 that have H 2 blockers and everybody is there for a GI</p> <p>6 presentation like this, and I felt that it had been well</p> <p>7 vetted in terms of anybody saying that I had withheld</p> <p>8 something is like, I don't understand how you could say that,</p> <p>9 at that meeting.</p> <p>10 At the same time I was getting busier with other things</p> <p>11 I was doing and I was at the point of saying, I'm done</p> <p>12 consulting. I'm done consulting with this project and I'm</p> <p>13 done with most of the consulting I was doing outside of --</p> <p>14 well, most of the consulting I was doing. And so I -- you</p> <p>15 know, somewhere we looked back there and it had Silverstein</p> <p>16 will present at these. I never presented at these things</p> <p>17 because I basically said, I'll go to the FDA, I'll do the</p> <p>18 best I can to explain the rationale for six months, the</p> <p>19 rationale for why celecoxib is a superior drug to the other</p> <p>20 NSAIDs, and then that's probably going to be the end of my</p> <p>21 involvement.</p> <p>22 Q. So would it be fair to say that you came in for some</p> <p>23 criticism because the JAMA article -- some public criticism</p> <p>24 because the JAMA article didn't include the section that you</p> <p>25 requested regarding informative censoring?</p>
<p style="text-align: right;">170</p> <p>1 that. And at this point I had 15 years plus or minus</p> <p>2 experience with Geis. He is an extremely intense, extremely</p> <p>3 bright M.D., Ph.D. who works all the time. I attended many</p> <p>4 meetings with him and heard him talk to the investigators,</p> <p>5 the people who are really doing the work, the guys who -- men</p> <p>6 and women who enroll the patients in the studies. And I held</p> <p>7 him in nothing but the highest regard as a scientist and as a</p> <p>8 colleague.</p> <p>9 So in that sense, I did believe him, yes, I believed</p> <p>10 him. I feel like -- I still feel like Steve Geis, with what</p> <p>11 I know, Steve Geis is exemplary in clinical research. He is</p> <p>12 just one of the hardest working people I've ever met. And I</p> <p>13 never had cause to feel as if he was misleading me, never,</p> <p>14 and he never asked me ever to mislead anybody else. It</p> <p>15 was -- it was always handled in what I considered to be the</p> <p>16 most kosher, if you will, representation and relationship.</p> <p>17 So I did not feel that Dr. Geis had done something that was</p> <p>18 unfair to me or unfair to the medical community or patients.</p> <p>19 Q. (BY MR. MONTGOMERY) Did you ever work with Dr. Geis again</p> <p>20 after the CLASS study?</p> <p>21 A. No.</p> <p>22 Q. Why is that?</p> <p>23 A. Well, you know, it wasn't a positive experience. What</p> <p>24 happened wasn't positive. It took a little bit of a life of</p> <p>25 its own. The media got involved. I mean, the entire study</p>	<p style="text-align: right;">172</p> <p>1 A. Yeah, but -- yes, that's fair to say. But -- go ahead.</p> <p>2 Finish your question.</p> <p>3 Q. So in that case why did you never publicly say, I asked for</p> <p>4 it to be in there but they didn't include it? Wouldn't that</p> <p>5 have gotten you off the hook publicly?</p> <p>6 MR. WEISS: Object to the form of the</p> <p>7 question.</p> <p>8 MR. BUSHOFSKY: Object.</p> <p>9 THE WITNESS: I don't feel like I was</p> <p>10 attacked personally. I felt like the whole paper was</p> <p>11 attacked. I was not a statistician of the paper. I was not</p> <p>12 a clinical trial expert. I was not a design expert. I was</p> <p>13 an expert in GI bleeding. Probably one of the experts in the</p> <p>14 world in GI bleeding if only by the fact that I'm old and</p> <p>15 I've done a lot of stuff, okay? So in therapy and diagnosis</p> <p>16 and epidemiology, and I know a lot about GI bleeding. I</p> <p>17 don't know these other things.</p> <p>18 So I never felt that I was attacked personally. You</p> <p>19 know, I never felt that -- I mean perhaps other people would</p> <p>20 say, Yeah, you were, but I didn't feel that way. And once it</p> <p>21 had been laid out to -- at the FDA, I felt it was clear and</p> <p>22 it was not necessary for me to go public and say something</p> <p>23 else because I felt it was -- it was there. It was there for</p> <p>24 everybody to read.</p> <p>25 Now, I did get involved again when the whole thing</p>



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<p style="text-align: right;">173</p> <p>1 heated up that next summer because initially there was -- you</p> <p>2 know, to me, I don't know how you could have had more data</p> <p>3 about what happened than at the February meeting, but then</p> <p>4 later in that year in July it heated up again when several</p> <p>5 people, two or three people wrote letters to the editor of</p> <p>6 JAMA and they wanted to know about how come apparently the</p> <p>7 study was longer than was in the JAMA article. And then I</p> <p>8 got involved again intensively because I felt like everybody</p> <p>9 was kind of going like this (indicating) and they needed</p> <p>10 somebody to come in and say, Let's figure out what we should</p> <p>11 do. And I wrote the letter to the -- the response to the</p> <p>12 letter to the editor in JAMA which was published in about</p> <p>13 October in which we said, In retrospect yeah, we should have</p> <p>14 made it clear. We should have -- I didn't say, Hey, I didn't</p> <p>15 do that. I chose not to do that. I didn't do that, because</p> <p>16 I felt like, you know, we were a team doing this. But what I</p> <p>17 did say was, Yeah, it would have been better if we had let</p> <p>18 people know the exact timing of the study. And then we</p> <p>19 answered a couple of other questions -- and so I was involved</p> <p>20 then. And after that, that was the end in 199 -- in 2001 of</p> <p>21 my consulting for Searle Pfizer Pharmacia.</p> <p>22 Q. (BY MR. MONTGOMERY) So why would it have been better if you</p> <p>23 had included the information concerning the post six-month</p> <p>24 data?</p> <p>25 A. Rephrase the question. Why --</p>	<p style="text-align: right;">175</p> <p>1 Q. Let me finish that.</p> <p>2 A. I'm sorry.</p> <p>3 Q. Why did you believe it would have been better if the JAMA</p> <p>4 article included the information that you suggested it</p> <p>5 contain?</p> <p>6 A. Okay. Because if I had included -- or if we had included</p> <p>7 that, it might have stopped the lay press from going, Whew,</p> <p>8 this is hidden data, you know, these folks are not being</p> <p>9 forthcoming about all the data. And my feeling is if that</p> <p>10 had not happened, the paper would have -- would have been</p> <p>11 okay. Maybe not perfect. Life is not perfect. You know, in</p> <p>12 retrospect the people who pick through things can sometimes</p> <p>13 find things that would be better done. But this study was an</p> <p>14 unbelievable effort on the part of a huge number of people</p> <p>15 and I think the data was important. But I feel that if we</p> <p>16 had put in that section -- and then it's, you know, then you</p> <p>17 know. You know, I don't believe it, because they didn't give</p> <p>18 me the other data. Well, you could say, Well, yeah, okay,</p> <p>19 they said the data after six months had some problems in it</p> <p>20 because of this other phenomena. But I felt like that would</p> <p>21 have precluded some of what became a little bit out of</p> <p>22 control.</p> <p>MR. MONTGOMERY: I'd like to show the</p> <p>24 witness what's previously been marked as Wolfe Exhibit 3.</p> <p>25 Q. (BY MR. MONTGOMERY) Is Exhibit 3 the JAMA -- I'm sorry; Wolfe</p>
<p style="text-align: right;">174</p> <p>1 Q. Let me ask it differently.</p> <p>2 You said, and correct me if I'm wrong, that in your</p> <p>3 letter to the editor you conceded it would have been better</p> <p>4 if you had included other information, correct?</p> <p>5 A. Right.</p> <p>6 Q. What information are you talking about?</p> <p>7 A. Okay. I'm talking about a section that explained why we used</p> <p>8 six months instead of the whole data. Because -- because I</p> <p>9 feel -- and this may not be intuitively obvious to you, that</p> <p>10 the CLASS paper is a good paper, that the amount of effort</p> <p>11 that went into this was thousands of hours, mostly on the</p> <p>12 part of the patients, but then on the individual doctors and</p> <p>13 then -- I mean this was not Steve Geis and me. I mean there</p> <p>14 were thousands of hours that went into this. It was a huge</p> <p>15 trial of a really significant new approach to the problem of</p> <p>16 arthritis which continues to become an increasing problem in</p> <p>17 our society as, you know, the aging of the population. I</p> <p>18 have a new hip. I have an artificial hip on the right side.</p> <p>19 So I mean this is something that is getting more -- it's not</p> <p>20 diminishing, it's becoming more important. We have learned</p> <p>21 the importance of the nonsteroidal anti-inflammatory drugs.</p> <p>22 So I'm sorry; I distracted myself. You were asking?</p> <p>23 Q. Why you thought it would have been better had the JAMA</p> <p>24 article --</p> <p>25 A. Oh, yes.</p>	<p style="text-align: right;">176</p> <p>1 Exhibit 3 is the JAMA article we've been talking about?</p> <p>2 A. Yes.</p> <p>3 Q. Could you take a look at the Main Outcome Measure section on</p> <p>4 the first page?</p> <p>5 A. Yes.</p> <p>6 Q. Do you see the reference to the six-month treatment period?</p> <p>7 A. Yes.</p> <p>8 Q. Why is it that the treatment period is called six-month here</p> <p>9 but is described differently in the documents that we looked</p> <p>10 at earlier?</p> <p>MR. WEISS: Object to the form of the</p> <p>12 question.</p> <p>THE WITNESS: Which documents? Those</p> <p>14 press releases? I mean the pink slips?</p> <p>MR. MONTGOMERY: No, no, no. No.</p> <p>16 Q. (BY MR. MONTGOMERY) Why don't you take a look at the final</p> <p>17 report. I'm pretty sure that has it. Yeah, it's page Bates</p> <p>18 number ending 145 of Exhibit 66.</p> <p>19 A. Okay. I have 145.</p> <p>20 Q. Yes. Do you see the Treatment Period section at the bottom?</p> <p>21 A. Yes, I do. I do.</p> <p>22 Q. I'll read into the record an excerpt of the first sentence.</p> <p>23 It says, "The treatment period was the period during which</p> <p>24 study medication was taken. For each patient this period was</p> <p>25 scheduled to last for 52 or 65 weeks," et cetera.</p>



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<p style="text-align: right;">177</p> <p>1 So that's how it's described here in the final report, 2 and in the JAMA article it's called the six-month treatment 3 period. I'm wondering, why the disparity? 4 MR. WEISS: Object to the form of the 5 question. 6 THE WITNESS: I think it's the issue 7 we're discussing. I mean the decision was made to talk about 8 the six-month treatment period which was a piece of the 9 entire period and had there been another section it would 10 have been clear. 11 Q. (BY MR. MONTGOMERY) As it stands could a reader of the JAMA 12 article have reasonably believed that the CLASS study only 13 lasted six months? 14 MR. WEISS: Object to the form of the 15 question. 16 THE WITNESS: Yes. 17 Q. (BY MR. MONTGOMERY) All right. Would you turn to page Bates 18 number ending 881? 19 MR. BUSHOFSKY: Which document? 20 MR. MONTGOMERY: I'm sorry; of Wolfe 21 Exhibit 3. 22 THE WITNESS: (Complies.) 23 Q. (BY MR. MONTGOMERY) Do you see Figure 1 at the top of the 24 page? 25 A. I do.</p>	<p style="text-align: right;">179</p> <p>1 question. 2 THE WITNESS: Well, it's talking about 3 the six-month period so it would be talking about -- I 4 believe there was an earlier chart which looked at six 5 months, so 4573. 6 Q. (BY MR. MONTGOMERY) So it would be appropriate to say that 7 4573 patients completed the study? 8 MR. WEISS: Object to the form of the 9 question. 10 MR. BUSHOFSKY: Object to the form. 11 THE WITNESS: No, completed six months. 12 Q. (BY MR. MONTGOMERY) So do you believe it would be inaccurate 13 to say -- to represent that over 4,000 patients completed the 14 study when -- let me rephrase. 15 Would it be inaccurate to say in the JAMA article that 16 over 4,000 patients completed the study? 17 A. It would not be inaccurate if you defined the study as the 18 six months. 19 Q. Do you believe that the JAMA article did that? 20 A. I think it did define it as six months. 21 Q. So then you think it's appropriate for the JAMA article to 22 represent that over 4,000 patients completed the study? 23 MR. WEISS: Object to the form of the 24 question. 25 THE WITNESS: Completed the six months of</p>
<p style="text-align: right;">178</p> <p>1 Q. And is that a flow chart of patient disposition at six 2 months? 3 A. I can't read it. 4 Q. Even the top part? 5 A. Oh, it says, "Flow chart of patient disposition at six 6 months," yes. But I can't read anything that's below it. 7 Q. Okay. Do you recall our discussion of the number of patients 8 that completed the study from the final report earlier? 9 A. Not specifically. 10 Q. All right. Let's take a look at it. 11 A. Okay. 12 Q. Let's look at the final report and I believe it's Page 57. 13 Actually it's Page 59. I'm sorry; Bates number ending 170 of 14 Exhibit 66. 15 MS. McPHEE: 170? 16 MR. MONTGOMERY: Yes. 17 THE WITNESS: Okay. 18 Q. (BY MR. MONTGOMERY) And do you see Figure 7 B there? 19 A. Yes. 20 Q. All right. At the bottom it says 3409 patients completed the 21 study? 22 A. Yes. 23 Q. All right. In Figure 1 of the JAMA article, how many 24 patients should it have said completed the study? 25 MR. WEISS: Object to the form of the</p>	<p style="text-align: right;">180</p> <p>1 the study. 2 Q. (BY MR. MONTGOMERY) Right. That's -- it could have said 3 that; I'm asking you would it be appropriate to say that over 4 4,000 patients completed the study? 5 A. And where does it say that? You're adding up the two boxes 6 on the bottom that I can't read of that flow chart? 7 Q. That's correct. 8 A. Well, this is what happened at six months. I feel like 9 that's accurate. Again, I would have preferred an additional 10 section. 11 Q. So you think it was accurate if it's -- strike that question. 12 You think it would be accurate to represent in the JAMA 13 article that over 4,000 patients completed the study, without 14 qualification? 15 MR. BUSHOFSKY: Object to the form. 16 THE WITNESS: My answer remains the same 17 as defined in this paper; six months, yes, it was over 4,000 18 patients who completed six months. I don't know how to say 19 it any differently. 20 Q. (BY MR. MONTGOMERY) Okay. Let's look at another page of the 21 final report, Bates number ending 177 of Exhibit 66. 22 A. Okay. Are we talking about Figure 8 A? 23 Q. Yes. Hold on one second. Actually let's turn to page Bates 24 number ending Page 182 of Exhibit 66. Do you see Figure 8 B 25 there?</p>



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<p style="text-align: right;">181</p> <p>1 A. I do.</p> <p>2 Q. All right. Do you see the box in the lower right-hand</p> <p>3 portion of Figure 8 B that says, "N equals 384 reviewed by</p> <p>4 all GEC members"?</p> <p>5 A. Yes.</p> <p>6 Q. And does that mean that for the entire study period the GEC</p> <p>7 reviewed the records of 384 patients?</p> <p>8 A. I believe that's right.</p> <p>9 Q. Let's look back at the JAMA article.</p> <p>10 A. Yeah.</p> <p>11 Q. Which is Wolfe Exhibit 3 at the page you're on, ending Bates</p> <p>12 No. 881. Do you see in the lower right-hand corner it</p> <p>13 says -- there's a section titled GI Toxicity?</p> <p>14 A. Yes.</p> <p>15 Q. All right. I'll read the first sentence of that into the</p> <p>16 record. "A total of 260 cases were selected by the GI events</p> <p>17 committee for adjudication."</p> <p>18 Do you see that?</p> <p>19 A. I do.</p> <p>20 Q. And is that an accurate statement?</p> <p>21 A. Well, I want to go back to the other flow chart.</p> <p>22 Q. Sure. That's on Bates No. 177 of Exhibit --</p> <p>23 A. Right.</p> <p>24 Q. -- 66?</p> <p>25 A. "A total of 260 cases were selected for adjudication."</p>	<p style="text-align: right;">183</p> <p>1 on Wolfe Exhibit 3, Bates number ending 882. Do you see</p> <p>2 Figure 2?</p> <p>3 A. I do.</p> <p>4 Q. Do you see Subsection B of Figure 2?</p> <p>5 A. I do.</p> <p>6 Q. All right. The first comparison there as between celecoxib</p> <p>7 and NSAIDs, do you see that?</p> <p>8 A. Right, I do.</p> <p>9 Q. And the P value is .04, correct?</p> <p>10 A. Correct.</p> <p>11 Q. And that's statistically significant, right?</p> <p>12 A. Correct.</p> <p>13 Q. Now, that result wouldn't be significantly significant if the</p> <p>14 data from the entire study period were included; is that</p> <p>15 right?</p> <p>16 A. That's my understanding.</p> <p>17 Q. Do you think it was misleading to represent this result</p> <p>18 without the section that you suggested be included concerning</p> <p>19 informative censoring?</p> <p>20 MR. WEISS: Object to the form of the</p> <p>21 question.</p> <p>22 THE WITNESS: I'm sorry. That -- I</p> <p>23 didn't follow the logic of what you said. This is looking at</p> <p>24 patients not taking aspirin and saying that in the six months</p> <p>25 of the trial that was presented here, there was a significant</p>
<p style="text-align: right;">182</p> <p>1 That is correct in the first six-month analysis.</p> <p>2 That's -- the N is equal to 260. Reviewed by the GEC</p> <p>3 members.</p> <p>4 Q. Right. Now, does the JAMA article say that 260 cases were</p> <p>5 reviewed in the first six months?</p> <p>6 A. It just says they were reviewed. It does not say in the</p> <p>7 first six months.</p> <p>8 Q. So would you expect a reader to take that to mean in the</p> <p>9 entire study 260 cases were reviewed?</p> <p>10 MR. BUSHOFSKY: Object to the form.</p> <p>11 MR. WEISS: Object to the form.</p> <p>12 THE WITNESS: I would think that the</p> <p>13 reader would think in the six months that's the number of</p> <p>14 cases that were reviewed. So I didn't follow exactly but</p> <p>15 that's my answer.</p> <p>16 Q. (BY MR. MONTGOMERY) Do you think that the representation that</p> <p>17 260 cases were selected by the GI events committee for</p> <p>18 adjudication was misleading without the section that you</p> <p>19 wanted included about informative censoring?</p> <p>20 MR. WEISS: Object to the form of the</p> <p>21 question.</p> <p>22 THE WITNESS: I think it's accurate</p> <p>23 because this paper is about six months. I feel it would have</p> <p>24 been better if there had been the other section added to it.</p> <p>25 Q. (BY MR. MONTGOMERY) All right. Let's take a look at Figure 2</p>	<p style="text-align: right;">184</p> <p>1 reduction in the incidence of upper GI complications in the</p> <p>2 patients not taking aspirin, so --</p> <p>3 Q. (BY MR. MONTGOMERY) Sure. Let me explore.</p> <p>4 A. Yeah.</p> <p>5 Q. This particular result was statistically significant at six</p> <p>6 months but not at the full data set, correct?</p> <p>7 A. Ah, I think you're addressing the fact that this was the only</p> <p>8 finding I believe that was significant at six months but</p> <p>9 not -- is that right? Not significant at the whole data set?</p> <p>10 Q. That's my understanding. You're free to -- you can look at</p> <p>11 the final report or any other document if you want to refresh</p> <p>12 your memory.</p> <p>13 A. Yeah, I think that's the case, okay.</p> <p>14 Q. So my question is, Figure 2 of the JAMA article, Wolfe</p> <p>15 Exhibit 3, displays a result that's only statistically</p> <p>16 significant at six months but not in the entire data set,</p> <p>17 correct?</p> <p>18 A. I -- okay. I'll take that as correct.</p> <p>19 Q. All right. In your opinion was it misleading to present this</p> <p>20 result without your, the section that you suggested be</p> <p>21 included explaining the reasons for the six-month analysis?</p> <p>22 A. No, because I feel like this is what happened at six months.</p> <p>23 This is what happened. In people not taking aspirin there</p> <p>24 was a significant improvement when you didn't have aspirin</p> <p>25 bollixing up the selectivity of the celecoxib. So I feel</p>



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<p>185</p> <p>1 like that's appropriate. However, I still would have</p> <p>2 preferred to have that section in saying that this was the</p> <p>3 first six months of what was a longer study. I don't think</p> <p>4 it makes this wrong. I think this is correct. And if I had</p> <p>5 to design the trial, I wouldn't have put -- I wouldn't have</p> <p>6 allowed patients on aspirin in the first place. I think.</p> <p>7 Q. All right. If you can turn the page on Wolfe Exhibit 3 to</p> <p>8 the next page I think, it's a Bates number ending 883.</p> <p>9 There's Table 4 there, do you see that?</p> <p>10 A. I do.</p> <p>11 Q. And I'd like you to compare that to the table in the final</p> <p>12 report which is Exhibit 66 on Bates number ending 288.</p> <p>13 A. I'm lost.</p> <p>14 Q. All right.</p> <p>15 A. I know you're saying you want me to compare this to the final</p> <p>16 report.</p> <p>17 Q. Right. Bates number ending 288.</p> <p>18 A. 288, okay. Okay.</p> <p>19 Q. All right. Do you see Table 10b in the final report?</p> <p>20 A. I do.</p> <p>21 Q. All right. And you see Table 4 in the JAMA article?</p> <p>22 A. I do.</p> <p>23 Q. All right. Now, Table 4 in the JAMA article discloses</p> <p>24 adverse effects during the six-month treatment period,</p> <p>25 correct?</p>	<p>187</p> <p>1 understand -- it's not as if something appeared in the entire</p> <p>2 data set on Table 4 -- excuse me -- on Table 10b that was not</p> <p>3 included in Table 4. So what I'm saying is Table 4 contained</p> <p>4 rash that occurred within six months. Table 10b mentioned a</p> <p>5 rash that occurred in the entire study period.</p> <p>6 So you're asking why not put the entire study period</p> <p>7 rash information into the article, but the article was about</p> <p>8 six months and there wasn't to me a significant difference,</p> <p>9 so why would you?</p> <p>10 Q. All right. Let me ask it a different way.</p> <p>11 If informative censoring is correct then the</p> <p>12 gastrointestinal results of the study became biased</p> <p>13 especially after six months, correct?</p> <p>14 A. Right.</p> <p>15 Q. But the -- is there any reason to believe that the safety</p> <p>16 results became biased after six months except with regard to</p> <p>17 GI events?</p> <p>18 A. Not to my knowledge.</p> <p>19 Q. So is there any reason to have excluded the non GI adverse</p> <p>20 event data from the post six-month period of the CLASS study?</p> <p>21 A. That's a very complicated sentence.</p> <p>22 MR. MONTGOMERY: She can read it back. I</p> <p>23 don't want to try it again.</p> <p>24 ///</p> <p>25 ///</p>
<p>186</p> <p>1 A. Correct.</p> <p>2 Q. And Table 10b in the final report discloses adverse events</p> <p>3 with incidence greater or equal to three percent in any</p> <p>4 treatment group for the entire study period, correct?</p> <p>5 A. Correct.</p> <p>6 Q. Now, why not include the adverse effects in the JAMA article</p> <p>7 that happened after six months?</p> <p>8 A. Like, for example?</p> <p>9 Q. Sure. Rash, for example?</p> <p>10 A. Just a moment. So you're saying rash is included in 10b in</p> <p>11 the final report but not included --</p> <p>12 Q. Oh, no, I'm sorry.</p> <p>13 A. -- in Table 4?</p> <p>14 Q. No, no, no. My question is, Table 4 of the JAMA article</p> <p>15 contains information regarding adverse rash events --</p> <p>16 A. Right.</p> <p>17 Q. -- during the first six months --</p> <p>18 A. Right.</p> <p>19 Q. -- of the study.</p> <p>20 A. Right.</p> <p>21 Q. Is there any reason not to have included rash adverse events</p> <p>22 that happened after six months in the study?</p> <p>23 A. The study represents six months and this rash information is</p> <p>24 complete. The Table 10b represents the entire study period</p> <p>25 and the data is very similar, as I read it. So I don't</p>	<p>188</p> <p>1 (Question on Page 187, Lines 19</p> <p>2 through 20, read by the</p> <p>3 reporter.)</p> <p>4 THE WITNESS: Right. What I would say is</p> <p>5 that would be a bit confusing because it wasn't the same</p> <p>6 period as the period for which the paper was written, and</p> <p>7 since there wasn't any substantial or important clinical</p> <p>8 difference, I don't see why you would do that. I don't see</p> <p>9 why you would make the paper about six months and write the</p> <p>10 adverse effects about the entire treatment period.</p> <p>11 MR. MONTGOMERY: I'd like to show the</p> <p>12 witness what's previously been marked Exhibit 4. I'm sorry;</p> <p>13 Wolfe Exhibit 4.</p> <p>14 MR. BUSHOFSKY: Before you get into that</p> <p>15 can we take a break?</p> <p>16 MR. MONTGOMERY: Sure. Let's go off the</p> <p>17 record, please.</p> <p>18 THE VIDEOGRAPHER: We're going off the</p> <p>19 record. The time is 2:59 p.m.</p> <p>20 (Recess 2:59-3:08.)</p> <p>21 THE VIDEOGRAPHER: We are back on the</p> <p>22 record. The time is 3:08 p.m. This is the beginning of Tape</p> <p>23 No. 5.</p> <p>24 ///</p> <p>25 ///</p>



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<p>189</p> <p>1 EXAMINATION (Continuing)</p> <p>2 BY MR. MONTGOMERY:</p> <p>3 Q. You understand you're still under oath?</p> <p>4 A. I do.</p> <p>5 Q. Okay. When we left we were looking at Wolfe Exhibit 4. Have</p> <p>6 you seen Wolfe Exhibit 4 before?</p> <p>7 A. I have.</p> <p>8 Q. And it's an editorial written by David R. Lichtenstine and M.</p> <p>9 Michael Wolfe concerning the JAMA article?</p> <p>10 A. Correct.</p> <p>11 Q. All right. Would you take a look on the first page of Wolfe</p> <p>12 Exhibit 4 -- well, before -- before we get there, did you see</p> <p>13 this editorial at the time it was published?</p> <p>14 A. You know, I think I did. I probably did. I don't remember</p> <p>15 studying it.</p> <p>16 Q. All right. Would you take a look on the first page of Wolfe</p> <p>17 Exhibit 4, the second column, so the column on the right,</p> <p>18 first full paragraph?</p> <p>19 A. Right.</p> <p>20 Q. Do you see in basically the middle of that paragraph there's</p> <p>21 a reference to the CLASS study as a six-month study?</p> <p>22 A. Right.</p> <p>23 Q. And is that an accurate description of the CLASS study?</p> <p>24 A. It says that in the journal I am reporting the results of a</p> <p>25 six-month randomized trial. That is true. That's what I</p>	<p>191</p> <p>1 THE WITNESS: Yes.</p> <p>2 Q. (BY MR. MONTGOMERY) Would it be fair to say that in the JAMA</p> <p>3 article you reported the results of a six-month study?</p> <p>4 MR. WEISS: Object to the form of the</p> <p>5 question.</p> <p>6 THE WITNESS: You're shaving the</p> <p>7 semantics a little bit for me, but I would think yes, that's</p> <p>8 true as well.</p> <p>9 Q. (BY MR. MONTGOMERY) Okay. So did you attend an advisory</p> <p>10 committee meeting at the FDA regarding Celebrex in February</p> <p>11 of 2001?</p> <p>12 A. I did.</p> <p>13 Q. And did you participate in rehearsals in anticipation of that</p> <p>14 meeting?</p> <p>15 A. I don't remember. I remember the meeting but I don't</p> <p>16 remember whether we had any rehearsals. I don't believe that</p> <p>17 we did but I don't remember it clearly.</p> <p>18 MR. MONTGOMERY: I'd like to ask the</p> <p>19 court reporter to mark what will be Exhibit 201.</p> <p>20 (Exhibit No. 201 marked</p> <p>21 for identification.)</p> <p>22 MR. MONTGOMERY: Oh, shoot. I think</p> <p>23 there's an e-mail stapled to the back of this that's not part</p> <p>24 of it. So that's what I'd ask people to do. So for the</p> <p>25 record Exhibit 201 is Bates No. DEFS 00656585 through</p>
<p>190</p> <p>1 reported in the journal. The trial obviously went on longer,</p> <p>2 so it could be, you know.</p> <p>3 Q. So would it be fair to say that you reported six months of a</p> <p>4 randomized trial? I'm sorry; let me say it differently.</p> <p>5 Would it be fair to say that in the JAMA article you</p> <p>6 reported the results -- six months -- strike that.</p> <p>7 Would it be fair to say that in the JAMA article you</p> <p>8 reported six months of the results of the CLASS study?</p> <p>9 A. Yes.</p> <p>10 MR. WEISS: Object to the form of the</p> <p>11 question.</p> <p>12 Q. (BY MR. MONTGOMERY) Would it be fair to say that in the JAMA</p> <p>13 article you reported the results of a six-month study?</p> <p>14 MR. WEISS: Object to the form of the</p> <p>15 question.</p> <p>16 THE WITNESS: Was that a different</p> <p>17 question than the one you asked first?</p> <p>18 Q. (BY MR. MONTGOMERY) Yes. Let me -- I'll ask them both</p> <p>19 again --</p> <p>20 A. Okay.</p> <p>21 Q. -- so you can -- would it be fair to say that in the JAMA</p> <p>22 article you reported six months of the results of the CLASS</p> <p>23 study?</p> <p>24 MR. WEISS: Object to the form of the</p> <p>25 question.</p>	<p>192</p> <p>1 00656587.</p> <p>2 Q. (BY MR. MONTGOMERY) Does Exhibit 201 appear to be notes by</p> <p>3 you regarding an advisory committee rehearsal on January 9th,</p> <p>4 2001?</p> <p>5 A. No.</p> <p>6 Q. Okay. Well, what do you think it is, if you know?</p> <p>7 A. I have no idea. I don't know where that Fred came from.</p> <p>8 It's like, Below are notes of observations. I hope these are</p> <p>9 helpful, Fred. Or, Below are some notes or observations I</p> <p>10 made. I hope these are helpful. Fred. Because later on it</p> <p>11 talks about things that doesn't sound like it's me talking,</p> <p>12 consultant comment. Consultant can't say you're safer,</p> <p>13 consultant makes more use of the 12-month data. So no, I</p> <p>14 don't remember this. Lee Simon doesn't -- how can it say</p> <p>15 Fred when it says Lee Simon does endoscopy services as a</p> <p>16 surrogate marker for outcomes? So I don't know what this is.</p> <p>17 Q. Okay.</p> <p>18 MR. MONTGOMERY: I'd like to ask the</p> <p>19 court reporter to mark Exhibit 202, please.</p> <p>20 (Exhibit No. 202 marked</p> <p>21 for identification.)</p> <p>22 Q. (BY MR. MONTGOMERY) For the record, Exhibit 202 is Bates No.</p> <p>23 DEFS 00392205 through Bates number ending 246.</p> <p>24 MR. WEISS: And Matt, I don't know if it</p> <p>25 matters but wasn't this marked at Weiner already?</p>



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<p>193</p> <p>1 MR. MONTGOMERY: It could have been.</p> <p>2 THE WITNESS: It's a nice presentation.</p> <p>3 Q. (BY MR. MONTGOMERY) So you presented the results of the CLASS</p> <p>4 study at the American College of Physicians; is that correct?</p> <p>5 A. That is correct, as I remember.</p> <p>6 Q. And that was April 17th, 2000?</p> <p>7 A. I guess. It was 10 years ago, but that's what I gather.</p> <p>8 Q. All right. And Exhibit 202, there's an e-mail on the first</p> <p>9 page and after that there's a slide presentation. Are those</p> <p>10 your slides from the APC?</p> <p>11 A. These are the slides I showed. They are a combination of my</p> <p>12 slides and slides from the company.</p> <p>13 Q. And in these slides did you just discuss the six-month data</p> <p>14 or the entire data set?</p> <p>15 A. I discussed the six-month data; however, at the beginning of</p> <p>16 my presentation I stood up and said, This study went on for</p> <p>17 longer than six months but the data after six months is very</p> <p>18 difficult to interpret and therefore I'm going to focus on</p> <p>19 the six-month data.</p> <p>20 Q. So you put in basically orally the section that you wanted to</p> <p>21 include in the JAMA article?</p> <p>22 A. Yeah, it was a little brief from the standpoint of explaining</p> <p>23 why, but yes, I did do that. And Searle knew I was going to</p> <p>24 do it and nobody objected.</p> <p>25 Q. And did you -- beyond what you just said, did you disclose</p>	<p>195</p> <p>1 Page 177. I apologize.</p> <p>2 A. Oh, I see. Okay. Okay.</p> <p>3 Q. All right. So we're looking at Exhibit 66, Bates number</p> <p>4 ending 288, Table 10b, correct?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. And that has adverse events for the entire study</p> <p>7 period, correct?</p> <p>8 A. It does.</p> <p>9 Q. Now, we can go through it one by one if you want, but why</p> <p>10 don't you take a minute and compare the results or the</p> <p>11 information in Figure 10b in the final report to your slide</p> <p>12 and tell me whether you think that these are the six-month or</p> <p>13 complete study results.</p> <p>14 A. Matt, could you take me back to the slide that has the</p> <p>15 adverse events in the six-month period, the corollary of 10b?</p> <p>16 I forgot where that is. I think there's another slide, isn't</p> <p>17 there, that looks just like that?</p> <p>18 Q. I will take a look and see if I can find it for you.</p> <p>19 A. Somewhere I thought we saw that.</p> <p>20 Q. All right. I'm not sure if you're referring to the</p> <p>21 information in the JAMA article itself?</p> <p>22 A. No, I thought we were looking at this. We had a comparison</p> <p>23 of the six-month data and the 12 and the entire study data.</p> <p>24 I got a lot of stuff here in front of me so I'm not exactly</p> <p>25 clear about it. Of course the numbers are not exactly the</p>
<p>194</p> <p>1 any of the results of the study after six months --</p> <p>2 A. No.</p> <p>3 Q. -- or just that there existed results after six months?</p> <p>4 A. Correct.</p> <p>5 Q. So just to make sure the record is clear, so you disclosed</p> <p>6 the existence of some results after six months but not what</p> <p>7 those results were?</p> <p>8 A. That's correct. What I said was the data was very difficult</p> <p>9 to interpret and therefore I'm going to focus on the first</p> <p>10 six months of the study.</p> <p>11 Q. All right. Would you turn to page Bates number ending 236 of</p> <p>12 Exhibit 202.</p> <p>13 A. (Witness complies.)</p> <p>14 Q. And is that a slide entitled Most Common Adverse Events?</p> <p>15 A. It is.</p> <p>16 Q. All right. And is this slide reporting adverse events from</p> <p>17 the first six months of the trial or the entire data set?</p> <p>18 A. As I recall the first six months of the trial.</p> <p>19 Q. All right. And can you take a look at the final report,</p> <p>20 please, which is Exhibit 66 at Page 177.</p> <p>21 A. Okay.</p> <p>22 Q. All right. Would you compare -- and I can take you through</p> <p>23 them one by one, but will you just compare --</p> <p>24 A. I must be in the wrong place. 177?</p> <p>25 Q. I'm sorry; Bates number ending 288. It's the internal</p>	<p>196</p> <p>1 same. I mean they're very close but they're not exactly the</p> <p>2 same. For example -- let's see. Entire study period. We're</p> <p>3 trying to compare it to 10d? What's that slide under your</p> <p>4 left hand?</p> <p>5 Q. It's Table 10b from the final report.</p> <p>6 A. B, okay.</p> <p>7 Q. Bates number ending 288.</p> <p>8 A. I mean the numbers are not identical. They're very close but</p> <p>9 they're not identical. For example, any event is 81.8 and</p> <p>10 81.7. Diclofenac -- I mean celecoxib. Diclofenac is 82.8</p> <p>11 and 82.9, so the numbers are not identical but I don't</p> <p>12 know --</p> <p>13 Q. Okay. Why don't you do me a favor and take a look at the</p> <p>14 JAMA article again.</p> <p>15 A. Okay.</p> <p>16 Q. Which is Wolfe Exhibit 3.</p> <p>17 A. Okay.</p> <p>18 Q. On Bates number ending 883.</p> <p>19 A. Yes, okay. I have it now.</p> <p>20 Q. Table 4.</p> <p>21 A. Well, it doesn't have it broken down. Table 4 does not have</p> <p>22 it broke -- to my read does not have it broken down to</p> <p>23 diclofenac versus ibuprofen. It has celecoxib versus the</p> <p>24 NSAID group.</p> <p>25 Q. Right. The percentages in Table 4 of the JAMA article,</p>



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<p style="text-align: right;">197</p> <p>1     though, the percentages for the celecoxib group should 2     correspond -- 3     A. For the celecoxib group should correspond, so they're 4     different. Okay. 5     Q. So does this lead you to conclude that you reported the 6     adverse events for the entire study period at ACP? 7     A. It doesn't because I haven't -- I'm seeing that it's not the 8     same as the six-month period. I haven't seen that it's the 9     same as the entire data set unless I'm -- my brain is going 10    in a circle. Do you have the adverse events during the 11    entire data set? 12    Q. That should be -- I understand it to be Figure 10b from the 13    final report. 14           MR. BUSHOFSKY: To move things along, you 15    might want to draw his attention to this thing at the bottom 16    of the slide in the presentation about the nine months. 17           MR. MONTGOMERY: Okay. Good point. 18           THE WITNESS: All right. Thank you, 19    Jeff. 20           MR. BUSHOFSKY: Sure. 21           MR. MONTGOMERY: That's the best 22    objection ever. All right. 23           MR. BUSHOFSKY: Some objections are meant 24    to move things along. 25    Q. (BY MR. MONTGOMERY) All right. So we're on <u>Exhibit 202</u>,</p>	<p style="text-align: right;">199</p> <p>1     A. No. 2     Q. And who made the decision? 3     A. This is -- can I explain one thing? 4     Q. Sure. 5     A. This is the kind of slide I can't make because I don't have 6     the data so somebody has to make up the slide and they gave 7     me the slide to present. I can't make up the slide myself. 8     So one would assume that Geis, Lefkowitz, you know, Ken 9     Verburg were the people who put this together and I either 10    wasn't aware or forgot that this was the data for the entire 11    study. 12    Q. Okay. And do you know, in the JAMA article, who made the 13    determination to put the adverse event information just for 14    six months? 15    A. I do not, except that was easier to understand since the 16    whole paper was about six months than this one why we went to 17    the full data set for the adverse events. It is a nice talk, 18    though. I'd love to take you through the entire talk. 19    Q. I'm sure you would. 20    A. Actually the reason I would is that it puts me on the bones 21    of what I said earlier about the other studies that have been 22    done about celecoxib. Okay. 23    Q. So did you attend the advisory committee meeting in February 24    of 2001? 25    A. I did.</p>
<p style="text-align: right;">198</p> <p>1     we're looking at page number ending 236 -- Bates Number. 2     A. Yes. 3     Q. So now do you believe that you're reporting adverse events 4     from the entire -- entire study period? 5     A. Just one moment. Yes. It's slightly different than the six 6     months, so yes, and especially with Jeff's note that it says 7     exposure nine months, right. 8     Q. Okay. So in your slide presentation to the ACP -- 9     A. Right. 10    Q. -- you reported the ulcer results for six months, correct? 11    A. Correct. 12    Q. But the rest of the adverse events for the entire data set, 13    correct? 14    A. That's correct. 15    Q. And in the JAMA article you reported the ulcer results for 16    six months, correct? 17    A. Right. 18    Q. But in the JAMA article you reported the adverse events for 19    only six months? 20    A. Right. 21    Q. Why the difference? 22    A. I don't know. 23    Q. Do you know who made the determination -- well, do you know 24    who made the determination to report the adverse events for 25    the entire study period at the ACP?</p>	<p style="text-align: right;">200</p> <p>1     Q. Did you help present the CLASS information? 2     A. I did. 3     Q. Did you use slides at that presentation? 4     A. I did. 5     Q. Okay. 6           MR. MONTGOMERY: I'd like to ask the 7     court reporter to mark what will be <u>Exhibit 203</u>. 8           THE WITNESS: I would note that I got ill 9     during the presentation. I had the flu and I actually had to 10    step off the podium and go vomit. And so I really was sick 11    and so I was not there for the entire presentation of the -- 12    I don't remember if I presented the GI part and then during 13    the discussion had to excuse myself but I was ill. 14    Q. (BY MR. MONTGOMERY) Okay. 15           (Exhibit No. 203 marked 16           for identification.) 17    Q. (BY MR. MONTGOMERY) Were these the slides presented by 18    Dr. Needleman, Geis, Lefkowitz and yourself at the advisory 19    committee meeting? 20    A. It looks like that, yes. 21    Q. All right. Would you turn to Page 78 of <u>Exhibit 203</u>. 22    A. I don't have page numbers. Oh, yes, maybe I do. 23    Q. In the lower left-hand corner. 24    A. Yeah, I do. Sorry. Okay. 25    Q. Do you see the slide entitled CLASS Committees?</p>



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<p style="text-align: right;">201</p> <p>1 A. I do.</p> <p>2 Q. And on the executive committee Dr. Lefkowitz isn't listed; do</p> <p>3 you see that?</p> <p>4 A. I do.</p> <p>5 Q. Do you know why that is?</p> <p>6 A. I do not.</p> <p>7 Q. Was he still a member of the executive committee at this</p> <p>8 point?</p> <p>9 A. It's not clear to me. He may have been a member, a non</p> <p>10 voting member. As we said earlier this morning, I read</p> <p>11 something that said he was a non voting member. So I don't</p> <p>12 know why his name wasn't on there. I did not make up that</p> <p>13 slide.</p> <p>14 Q. Okay. Let's -- will you turn to Page 97 of Exhibit --</p> <p>15 A. Just let me make one comment in this regard. The role of</p> <p>16 Searle in this study was very obvious in the sense that they</p> <p>17 were half the authors on the paper and I think it said that</p> <p>18 we were paid consultants to Searle and I think it said that</p> <p>19 Searle paid for the study. So I mean there was never an</p> <p>20 attempt to obfuscate the fact that Searle was involved in the</p> <p>21 study. It was never an attempt to say that this was just all</p> <p>22 of us doing the study without Searle. I'm sorry; what page?</p> <p>23 Q. 97 of Exhibit 203.</p> <p>24 A. Okay.</p> <p>25 Q. Is that a slide entitled Ulcer Complications?</p>	<p style="text-align: right;">203</p> <p>1 don't see that anywhere appearing on this -- on this table,</p> <p>2 because the table is broken out by diclofenac and ibuprofen</p> <p>3 unless I'm not reading this correctly.</p> <p>4 Also complications, .4, all patients.</p> <p>5 Q. Obviously it says what it says, but in the Table 2 under All</p> <p>6 Patients for the number per 100 patient years, diclofenac</p> <p>7 is .93, right?</p> <p>8 A. Wait a minute. Where are you?</p> <p>9 Q. Table 2.</p> <p>10 A. Right.</p> <p>11 Q. Under All Patients.</p> <p>12 A. Just a minute. Okay.</p> <p>13 Q. And then the bottom of the diclofenac column there.</p> <p>14 A. So the number per --</p> <p>15 Q. Is .93?</p> <p>16 A. -- hundred patient years, so it's .73 for celecoxib which</p> <p>17 looks about what the bar graph looks like. And it's .93</p> <p>18 and .98 for the other two comparators. And so what you're</p> <p>19 saying is combined it would have been about .95, so it looks</p> <p>20 like that's what it is. It's ulcer complications for all</p> <p>21 patients, okay.</p> <p>22 Q. Okay. So going back to Exhibit 203, the slide on Page 97.</p> <p>23 A. Right.</p> <p>24 Q. Is it your belief now that that slide is showing results from</p> <p>25 the full study period, correct?</p>
<p style="text-align: right;">202</p> <p>1 A. Yes, it is.</p> <p>2 Q. All right. And is that the results from six months or the</p> <p>3 entire study period?</p> <p>4 A. I don't know.</p> <p>5 Q. All right. Let's take a look at --</p> <p>6 A. Maybe there's a concomitant slide that shows the other period</p> <p>7 of time.</p> <p>8 Q. All right. Let's take a look at the final report and I think</p> <p>9 we can figure it out.</p> <p>10 A. Okay.</p> <p>11 Q. So final report, Bates number ending 117.</p> <p>12 A. Okay. So Ulcer Complications, All Patients.</p> <p>13 Q. So I direct you to Table 2 for all patients, all the way to</p> <p>14 the right is the comparison between celecoxib and the</p> <p>15 combined NSAIDs. Do you see that?</p> <p>16 A. Yes.</p> <p>17 Q. And that P value is .45?</p> <p>18 A. Right.</p> <p>19 Q. And is that the same as shown on the slide from Exhibit --</p> <p>20 A. It is but I'm not sure it's the same slide anyway. Let me</p> <p>21 look for a minute.</p> <p>22 Q. Okay. Take your time.</p> <p>23 A. The problem is I don't see anywhere on this chart where -- I</p> <p>24 see celecoxib coming in at about .75 with the ordinate saying</p> <p>25 it's about .75, but the bar to the right is about .9 and I</p>	<p style="text-align: right;">204</p> <p>1 A. Yes, I think so.</p> <p>2 Q. Now, was there any -- are you aware of any decision by Searle</p> <p>3 or Pfizer to present the full study data at the advisory</p> <p>4 committee meeting?</p> <p>5 A. That's a complicated question because the FDA had all the</p> <p>6 data. Dr. Goldkind was the FDA GI reviewer. He said that he</p> <p>7 wanted to see all the data. So I don't think it was an</p> <p>8 internal discussion on the part of Searle, I think the FDA GI</p> <p>9 person said he wanted to see all the data, I think.</p> <p>10 Q. Let me put it a different way.</p> <p>11 As far as you know, at the advisory committee meeting,</p> <p>12 did any representative of Pfizer -- I'm sorry. Strike that.</p> <p>13 At the advisory committee meeting, did any</p> <p>14 representative of Pharmacia or Pfizer argue for the validity</p> <p>15 of the six-month analysis?</p> <p>16 A. I think so. As I remember, yes. Now, but I may be mixing</p> <p>17 that up with conversations with the FDA prior to the advisory</p> <p>18 meeting. Because Goldkind -- there was a question of what</p> <p>19 Goldkind was going to do and I think he was the one that came</p> <p>20 out saying he wanted to see all the data.</p> <p>21 Q. But you could have presented the full results and the</p> <p>22 six-month results at the same meeting, correct?</p> <p>23 A. And I don't know that we didn't do that. I don't know that.</p> <p>24 Q. I'm just asking you if you could have done that?</p> <p>25 A. I think so.</p>



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<p style="text-align: right;">205</p> <p>1 Q. Okay.</p> <p>2 A. Because at this meeting it was clear that the data that was</p> <p>3 presented was the whole trial and that the JAMA article had</p> <p>4 been the first six months.</p> <p>5 MR. MONTGOMERY: I'd like to ask the</p> <p>6 court reporter to mark <u>Exhibit 204</u>.</p> <p>7 (Exhibit No. 204 marked</p> <p>8 for identification.)</p> <p>9 THE WITNESS: Yes. Okay.</p> <p>10 Q. (BY MR. MONTGOMERY) And did Dr. Goldkind make a presentation</p> <p>11 at the advisory committee meeting?</p> <p>12 A. I think so.</p> <p>13 Q. And do these look like his slides?</p> <p>14 A. Beats me, but it looks like it. I don't remember the slides</p> <p>15 at all.</p> <p>16 Q. Just take a look through and let me know, is there any reason</p> <p>17 you think these aren't Dr. Goldkind's slides from the</p> <p>18 advisory meeting?</p> <p>19 MR. BUSHOFSKY: Objection.</p> <p>20 THE WITNESS: No.</p> <p>21 Q. (BY MR. MONTGOMERY) Did Dr. Witter make a presentation at the</p> <p>22 advisory committee meeting?</p> <p>23 A. I don't remember -- who is Dr. Witter? I don't remember.</p> <p>24 Q. Let me show you this and maybe it will refresh your memory.</p> <p>25 MR. MONTGOMERY: I'd like to ask the</p>	<p style="text-align: right;">207</p> <p>1 Q. All right. Do you see on Page 78 where your name appears?</p> <p>2 A. Yes, I do.</p> <p>3 Q. I'm going to -- so is that the beginning of your</p> <p>4 presentation?</p> <p>5 A. I don't know.</p> <p>6 Q. Okay. Take a look.</p> <p>7 A. I mean I don't know if I said anything earlier, but clearly</p> <p>8 this is me talking.</p> <p>9 Q. Okay. And then I'd like you to look a couple pages later on</p> <p>10 Page 81.</p> <p>11 A. Okay.</p> <p>12 Q. And according to the transcript this is still you talking,</p> <p>13 correct?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. And I'd like you to look at the statement starting on</p> <p>16 Page -- on Line 5 of Page 81.</p> <p>17 A. Okay.</p> <p>18 Q. It says, "And we allowed aspirin which I think is critical</p> <p>19 because you have already seen that it has a dramatic effect</p> <p>20 and I think it is an important part of a study of this type</p> <p>21 so I think it is an excellent trial design."</p> <p>22 Do you see that?</p> <p>23 A. I do.</p> <p>24 Q. Now, didn't you testify earlier that you -- in your opinion</p> <p>25 aspirin should have been excluded from the trial?</p>
<p style="text-align: right;">206</p> <p>1 court reporter to mark <u>Exhibit 205</u>. She's got to mark it.</p> <p>2 (Exhibit No. 205 marked</p> <p>3 for identification.)</p> <p>4 THE WITNESS: You know what? It is</p> <p>5 possible that I was ill when this was presented because I</p> <p>6 don't remember any picture of any wizard looking -- there's a</p> <p>7 picture of a wizard in here somewhere, a humorous slide I</p> <p>8 assume, and it's possible this was presented after I was ill.</p> <p>9 Q. (BY MR. MONTGOMERY) Okay. So you don't remember -- you can't</p> <p>10 tell me whether these are Dr. Witter's slides one way or the</p> <p>11 other?</p> <p>12 A. No, I cannot.</p> <p>13 Q. Okay. Have you ever seen a transcript of the advisory</p> <p>14 committee meeting?</p> <p>15 A. I have not.</p> <p>16 MR. MONTGOMERY: I'd like to ask the</p> <p>17 court reporter to mark what will be <u>Exhibit 207</u>. I'm sorry;</p> <p>18 206.</p> <p>19 (Exhibit No. 206 marked</p> <p>20 for identification.)</p> <p>21 Q. (BY MR. MONTGOMERY) All right. Does this appear to you to be</p> <p>22 a transcript of the advisory committee meeting?</p> <p>23 A. That's how it's labeled, yeah.</p> <p>24 Q. Okay. Would you take a look at Page 78 of <u>Exhibit 206</u>.</p> <p>25 A. (Witness complies.) Okay.</p>	<p style="text-align: right;">208</p> <p>1 A. My opinion right now is that having aspirin obfuscated the</p> <p>2 results of the trial. My opinion then was that I thought it</p> <p>3 was -- it was important, and let me explain why. You're</p> <p>4 trying to look at real world patients and this was a</p> <p>5 difference in the design of different trials, where here they</p> <p>6 designed this trial and they said, Let's take the three</p> <p>7 severe outcomes, let's not take symptomatic ulcers. Let's</p> <p>8 include people on aspirin even though it's probably going to</p> <p>9 obfuscate or make the trial more difficult. Let's take</p> <p>10 celecoxib but two to four times the dose which we would use.</p> <p>11 So they pushed the design on all three parameters or multiple</p> <p>12 parameters.</p> <p>13 Now, at the end, had it been successful you could have</p> <p>14 said, Hey, even in people on aspirin, even in people without</p> <p>15 symptomatic ulcers, even in people taking two to four times</p> <p>16 the dose of celecoxib, it was still significant. But that</p> <p>17 didn't happen, it was just short of significance. So you</p> <p>18 know, this is the art of controlled clinical trial design.</p> <p>19 I would say at this point in my life, which I'm</p> <p>20 entitled to have a different opinion than what I felt</p> <p>21 10 years ago, that it would have been a more clear study had</p> <p>22 we not permitted aspirin. Now, again, these older people --</p> <p>23 I take aspirin, me, Fred Silverstein, I take an 80-milligram</p> <p>24 aspirin, my wife takes aspirin every day. So a lot of people</p> <p>25 take these small dose of aspirin and so there was a rationale</p>



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<p style="text-align: right;">209</p> <p>1 for including aspirin. And if you say -- if you want to make 2 it real world, you should include aspirin. But with all the 3 kerfuffle about the interpretation of the data perhaps, I 4 feel like, wow, if we hadn't included aspirin it would have 5 taken that part out of it. 6 Q. The results of the trial didn't conform to your expectations; 7 is that a fair statement? 8 A. Expectations, I don't know. Did -- I hoped -- you know, the 9 reason I spent all the time on this was not for notoriety and 10 it was not for money. It was because I was 30 years into the 11 topic of gastrointestinal bleeding and all the different ways 12 we've discussed today, and I thought this drug was a 13 significant step forward. I was hoping that the results 14 would be clear and would leave no ambiguity. So in that 15 sense, yes, they were not as good as I was hoping they would 16 be, if that answers your question. 17 Q. Even -- and you knew that at the time of the advisory 18 committee meeting, right? 19 MR. WEISS: Object to the form of the 20 question. 21 THE WITNESS: When you say "that" what do 22 you mean? 23 Q. (BY MR. MONTGOMERY) The results of the study that you just 24 described? 25 A. Yes, yes.</p>	<p style="text-align: right;">211</p> <p>1 go back to what I said in here because I did address what 2 happened. I addressed why the CLASS trial didn't work and I 3 said, for example, that the risk factors were fewer. And I 4 mentioned that earlier today, that doctors have gotten smart 5 about not wanting to put patients at risk, and therefore, the 6 patients coming into the CLASS trial had a different risk 7 profile. So I -- I thought it was a pretty comprehensive 8 discussion of why the trial didn't come out the way we were 9 hoping it would come out. Okay. 10 Q. (BY MR. MONTGOMERY) Do you recognize <u>Exhibit 207</u>? 11 A. Yes. 12 Q. All right. And is this a fax to you from Steve Geis asking 13 you to review the rationale for the six-month analysis? 14 A. This was the point at which I decided that even though I had 15 not been consulting for Pharmacia any longer, I had to get 16 into this. So this is in that month of August where I told 17 you I actually had the month off from my work and I was going 18 to have a month to do other things and I wound up spending 19 the entire month working on this. So Steve -- I don't know 20 if it was a fax, maybe it was a -- I don't know if it was a 21 fax or an e-mail, but he sent this to me with what his 22 thoughts were about the six-month data in preparation for my 23 writing a response. It was one of the things that happened 24 of 50 or 75 things as I began to think about writing a 25 response to the letters to the editor of JAMA.</p>
<p style="text-align: right;">210</p> <p>1 Q. And even in light of those results, you still thought it was 2 an excellent trial design? 3 A. Well, I think those are two different questions. The result 4 of a trial and the trial design, I mean you don't design a 5 trial to get the results, you know, you don't -- you design a 6 trial because it's answering the question you want to answer, 7 and I felt in that sense, yes, it was a good design. It did 8 not come out the way I wanted it to, but aside from the 9 aspirin issue -- and I would have included symptomatic ulcers 10 as well, I felt overall that the trial design was fine. 11 And remember, there's a huge amount involved in the 12 trial design: Age of patients, number of centers, number of 13 patients, underlying disease, concomitant medications, 14 steroids. I mean there are a thousand variables that have to 15 be considered in a trial design, it's not just, yes, aspirin; 16 yes, no, symptomatic ulcers; yes, no -- you know, there 17 are -- there are literally hundreds of moving parts in the 18 design of a trial like this and I thought it was reasonable 19 even though it didn't come out the way I wanted it to come 20 out. 21 MR. MONTGOMERY: I'd like to ask the 22 court reporter to mark what will be <u>Exhibit 207</u>. 23 (<u>Exhibit No. 207</u> marked 24 for identification.) 25 THE WITNESS: Just before that, I want to</p>	<p style="text-align: right;">212</p> <p>1 Q. Was there any information in <u>Exhibit 207</u> that you didn't have 2 at the time the JAMA article was published? 3 A. I have to review it for a moment. 4 Q. Take your time. 5 A. (Witness complies.) 6 You know, I don't know that I had seen every one of 7 these slides in this format but I did not feel at the time, 8 and I can't comment on it now because I don't have any basis 9 for which to make a comparison, but I did not feel at the 10 time that they surprised me with any data, if that answers 11 your question. 12 Q. It sounds like the best we're going to do 10 years later. 13 A. Yeah. Literally more than 10 years. Well, nine plus. 14 Q. Did you have a call with Barbara DeAngelo at some point 15 before -- 16 A. I did. 17 Q. Let me finish the question. Did you have a call with Barbara 18 DeAngelo about the JAMA paper at some point before you 19 submitted your letter to the editor? 20 A. I did. My response to the letter of the editor. 21 Q. And what precipitated that call? 22 A. Dr. DeAngelo heard sometime in the late spring, early summer 23 that there was this issue being raised about whether all the 24 data was presented in the CLASS paper, and as I remember a 25 couple of Searle people went to JAMA to discuss it with her</p>



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Fred Silverstein

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<p style="text-align: right;">213</p> <p>1 in person and what she said is, Where is Dr. Silverstein? He</p> <p>2 was the first author of the paper, why isn't he here? So I</p> <p>3 felt that at a minimum I needed to call her and then maybe</p> <p>4 potentially to go to Philadelphia to meet with her in person.</p> <p>5 So either she called me or I called her and we talked for</p> <p>6 about a half-hour.</p> <p>7 Q. Why weren't you at the meeting between Searle and</p> <p>8 Dr. DeAngeles?</p> <p>9 A. I don't think I knew it was about to happen. I don't</p> <p>10 remember.</p> <p>11 Q. Okay.</p> <p>12 MR. MONTGOMERY: I'd like to ask the</p> <p>13 court reporter to mark what will be <u>Exhibit 208</u>.</p> <p>14 (Exhibit No. 208 marked</p> <p>15 for identification.)</p> <p>16 THE WITNESS: Okay. Yes.</p> <p>17 Q. (BY MR. MONTGOMERY) Is <u>Exhibit 208</u> a fax regarding your call</p> <p>18 with Dr. DeAngeles?</p> <p>19 A. No. <u>Exhibit 208</u> has a brief fax on the front but the</p> <p>20 majority of the document are the notes that I made for myself</p> <p>21 while I was talking to Dr. DeAngeles.</p> <p>22 Q. Okay.</p> <p>23 A. And that's just a -- some people need to make notes while</p> <p>24 they're doing something and I'm one of them and I wrote these</p> <p>25 notes down. And I included it in the documents that I sent</p>	<p style="text-align: right;">215</p> <p>1 the middle that ends I believe, "Not want" --</p> <p>2 A. Erroneous or incomplete I think.</p> <p>3 Q. Okay. Could you just read that into the record?</p> <p>4 A. I'm a doctor so my handwriting is unintelligible to me,</p> <p>5 myself. So I think she said, "Where is Fred?" And then she</p> <p>6 said, "I want a new letter on Fred's letterhead mentioning</p> <p>7 both the clinical faculty at UW and a partner of Fraser &amp;</p> <p>8 Company," that's a company of which I was a partner. "Two</p> <p>9 issues." I don't remember what 2G was. I don't remember why</p> <p>10 I used that abbreviation. But one, "Did we have the 12-month</p> <p>11 data at the time we submitted the paper and why we didn't</p> <p>12 submit the 12-month data?"</p> <p>13 And then she said Dr. -- that "Fred's reputation is</p> <p>14 very good." She doesn't want an article to be incomplete --</p> <p>15 erroneous or incomplete. So that's what you asked me to read</p> <p>16 through.</p> <p>17 Q. Yep, that's fine. Thank you.</p> <p>18 MR. MONTGOMERY: At this point I'd like</p> <p>19 to ask the court reporter to mark what will be marked</p> <p>20 <u>Exhibit 210</u>.</p> <p>21 (Exhibit No. 210 marked</p> <p>22 for identification.)</p> <p>23 Q. (BY MR. MONTGOMERY) Is <u>Exhibit 210</u> a letter from</p> <p>24 Dr. Lefkowitz to you dated -- well, undated letter?</p> <p>25 A. Yeah, it's undated.</p>
<p style="text-align: right;">214</p> <p>1 for this because you had asked for everything and so I sent</p> <p>2 everything.</p> <p>3 Q. Yeah, you know, I'm glad you mentioned that because I see</p> <p>4 there's some irregularity here anyway. So just take off the</p> <p>5 first page. They're not consecutive for some reason.</p> <p>6 A. Okay.</p> <p>7 Q. And I'm going to call <u>Exhibit 208</u> the fax that you described</p> <p>8 which is Silverstein 00077.</p> <p>9 MR. MONTGOMERY: Then I'm going to ask</p> <p>10 the court reporter to mark as <u>Exhibit 209</u> the notes that you</p> <p>11 were discussing.</p> <p>12 (Exhibit No. 209 marked</p> <p>13 for identification.)</p> <p>14 Q. (BY MR. MONTGOMERY) All right. So <u>Exhibit 209</u> are the notes</p> <p>15 you took during your conversation with Dr. DeAngeles?</p> <p>16 A. Correct.</p> <p>17 Q. Okay. Would you look at the third page, Bates No. 092</p> <p>18 Silverstein?</p> <p>19 A. Of 209?</p> <p>20 Q. Yes.</p> <p>21 A. Okay.</p> <p>22 Q. Do you see towards the top of the page where it starts,</p> <p>23 "Wants new letter"?</p> <p>24 A. Yes.</p> <p>25 Q. All right. Could you read that section all the way through</p>	<p style="text-align: right;">216</p> <p>1 THE WITNESS: Do you know the date of the</p> <p>2 letter? Did this come from me when I sent the whole clump of</p> <p>3 stuff or do you know what the origin of it was?</p> <p>4 Q. (BY MR. MONTGOMERY) According to the Bates number, it was</p> <p>5 produced by you.</p> <p>6 A. Okay. So I had this in my file and sent it to you, but I</p> <p>7 don't know what the date is.</p> <p>8 Q. All right. Do you see on the first page of <u>Exhibit 210</u> the</p> <p>9 third paragraph starting at, "Special communication"?</p> <p>10 A. Yes. I don't know what year that was.</p> <p>11 Q. All right. Let's look at the second page. This is the</p> <p>12 second page of <u>Exhibit 210</u>, Bates number ending 129. Do you</p> <p>13 see the third full paragraph or the third paragraph on the</p> <p>14 page starting, "Recent commentaries"?</p> <p>15 A. Yes.</p> <p>16 Q. And it talks about the September 13th, 2000 edition of JAMA?</p> <p>17 A. Correct.</p> <p>18 Q. So does that lead you to believe it was after the publication</p> <p>19 of the JAMA article?</p> <p>20 A. Yeah. That, yes. When, I don't know.</p> <p>21 Q. And do you have any idea why Dr. Lefkowitz sent you this</p> <p>22 letter?</p> <p>23 A. You know, I -- I looked at this. I think it was a letter</p> <p>24 that wasn't just sent to me. It was sent to -- somewhere I</p> <p>25 thought it said it was -- "Given your" -- on the first page,</p>



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<p style="text-align: right;">217</p> <p>1 first paragraph, "Given your important role as a consultant 2 to Pharmacia, we would like to take this opportunity to 3 provide relevant data to you. We regret any confusion that 4 may have arisen and hope this information will enable you to 5 more effectively respond to queries in your role as a 6 consultant." 7 And it's from Jim and I don't know when Jim died so 8 that would be one way to know it was obviously pre mortem. 9 Do you know when he died? 10 Q. I don't. 11 THE WITNESS: Anybody? I don't know when 12 he died, so... 13 Q. (BY MR. MONTGOMERY) Let's take a look at the third page of 14 <u>Exhibit 210</u>, Bates No. Silverstein 00130. And do you see in 15 the top paragraph there it refers to the advisory committee 16 meeting, February 7, 2001? 17 A. Yes. 18 Q. So do you take that to mean -- 19 A. Yes. Sorry. 20 Q. -- that the letter was written after that meeting? 21 A. Yes. 22 Q. Okay. I'd like you to take a look at the tables that are 23 attached and my question to you is whether they contain any 24 information that you didn't already have after the advisory 25 committee meeting?</p>	<p style="text-align: right;">219</p> <p>1 hard in this environment for me to pour over each one, is 2 that there was no difference between comparators for 3 thromboembolic events, et cetera. 4 Q. All right. 5 MR. MONTGOMERY: I'd like to ask the 6 court reporter to mark what will be <u>Exhibit 211</u>. 7 (<u>Exhibit No. 211</u> marked 8 for identification.) 9 Q. (BY MR. MONTGOMERY) <u>Exhibit 211</u>, more handwritten notes by 10 you? 11 A. Yes. 12 Q. And do you know what these notes are about? 13 A. Yes. 14 Q. What are they about? 15 A. The whole thing we've been talking about today. But I felt, 16 and I didn't date it because it was to myself, this was not 17 something that I intended anybody else to read, but this 18 whole episode was upsetting to me and I felt I needed to 19 write down the rationale for several things that we've 20 discussed today and that's what this is. Again, in the 21 interest of complete disclosure, I sent it to you guys even 22 though it was not something I intended. I didn't destroy it. 23 I sent it to you. 24 Q. Okay. What prompted you to write this down? 25 A. Nothing special, just me saying, I better -- you know, no</p>
<p style="text-align: right;">218</p> <p>1 A. Okay. You know, I think that these reports were derived from 2 the NDA summary to the FDA, but I don't remember seeing -- I 3 think the issue was -- there was a question about the 4 cardiovascular safety, as a matter of fact that's in this, 5 the beginning of the paper, and that they then put together 6 tables about the cardiovascular safety. So to answer your 7 question, the data was available; I'm not sure I saw it in 8 this form until I saw this. 9 Q. All right. Now, having gone through it, do you have any idea 10 why Dr. Lefkowitz was sending you this information? 11 A. That's the reason I would love to know what the date is, 12 because at the time of the FDA presentation and at the time 13 of my response to JAMA in August there was no indication or 14 signal that there was a problem with myocardial infarction, 15 stroke, clotting, et cetera. And I know that somebody had 16 written an editorial, somebody from the Cleveland Clinic or 17 something had written an editorial about COX-2 inhibitors 18 saying, you know, maybe there's an increased risk and that it 19 was worse for Vioxx than it was for Celebrex. 20 I don't remember the timing of that, and I think that 21 this is to the -- yeah, I would suspect this was kind of like 22 at the end of 2001 or in the beginning of 2002 but I don't 23 know for sure. I don't know. Addressing whether we did know 24 or not that there was any risk, and what he's concluding from 25 the bottom of each of these slides, because it's a little</p>	<p style="text-align: right;">220</p> <p>1 threat, no -- you know, nothing, just me saying, I think I 2 better write down what my thought process was in the process 3 of writing the response to the letters to the editor of JAMA. 4 I believe that's when I wrote it. 5 Q. Okay. So you think you wrote this during the process of 6 drafting your letter to JAMA -- 7 A. Yeah. 8 Q. -- about the JAMA article? 9 A. Yeah, I mean, for example, I wanted to remember that, you 10 know, if somebody asked me -- I didn't know that I'd be here 11 today, but if somebody asked me, Why wasn't the outcome as 12 clear -- look at No. 7 on the first page, Why wasn't the 13 outcome as clear as anticipated? And there were several 14 unpredicted factors: Aspirin use we talked about; fewer 15 patients as risk factors, we talked about; more patients 16 dropped out; and it looked like the complications virtually 17 stopped occurring, et cetera. So in other words, it was to 18 codify and refresh my memory about my thoughts about the 19 CLASS trial. 20 Q. Okay. Would you look at the second page of your notes, 21 <u>Exhibit 211</u>? 22 A. Sure. 23 Q. Can you read into the record, please, the note at the bottom 24 of the page that says K something? 25 A. Yes.</p>



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<p style="text-align: right;">221</p> <p>1 Q. Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. Can you just read that into the record through the end of the</p> <p>4 page?</p> <p>5 A. Sure. "K, several consultants and others wanted to add a</p> <p>6 section regarding timing of the first six months."</p> <p>7 I don't know what that word is. Hold on a minute. It</p> <p>8 was a rapid track and some confusion led to not including</p> <p>9 this section. That was the best that I could remind myself</p> <p>10 about why it wasn't included. I don't remember what --</p> <p>11 regarding timing, I don't know what I meant there.</p> <p>12 Q. All right. Do you understand that's a note to refer to the</p> <p>13 section you talked about earlier that you wanted in --</p> <p>14 A. Yes.</p> <p>15 Q. Let me finish the question.</p> <p>16 A. Okay.</p> <p>17 Q. Do you understand this note to refer to the section you</p> <p>18 talked about earlier wanting to include in the JAMA article</p> <p>19 regarding the justification for only publishing six months?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. Are you one of the consultants you're referring to in</p> <p>22 that note?</p> <p>23 A. Yes.</p> <p>24 Q. Who are the other ones?</p> <p>25 A. Don't remember.</p>	<p style="text-align: right;">223</p> <p>1 A. Okay. I don't see cross hatching.</p> <p>2 Q. The lining --</p> <p>3 A. Yes, okay. So it stops with -- no bias. There was no reason</p> <p>4 for us to be unethical. Nobody owned stock, et cetera.</p> <p>5 Q. Excuse me. You can of course explain whatever you want, but</p> <p>6 can you just read it into the record first so we know what</p> <p>7 your handwriting is and then you can expound if you want.</p> <p>8 A. "Tried to get the section in about the six months, greater</p> <p>9 than six months. It was a rapid track. There must have been</p> <p>10 a miscommunication. In the letters to the editor we said it</p> <p>11 would have been better."</p> <p>12 And that in fact is what I said. In retrospect it</p> <p>13 would have been better if we included a section explaining</p> <p>14 that.</p> <p>15 Q. Okay. Could you read the first of the page then?</p> <p>16 A. "Having greater than six months did not change the</p> <p>17 conclusion. The decision" -- "the decision to buy 30,000</p> <p>18 reprints had nothing to do with the consultants. There was</p> <p>19 no reason to be" -- I don't know what that -- inflammatory, I</p> <p>20 don't know what that means. "And even if we made a mistake</p> <p>21 it does not mean we were unethical. It could be it was" --</p> <p>22 "it could be you can have an error and it's not intentional."</p> <p>23 MR. MONTGOMERY: I'd like to ask the</p> <p>24 court reporter to now mark what will be <u>Exhibit 212</u>.</p> <p>25 ///</p>
<p style="text-align: right;">222</p> <p>1 Q. Okay. Having seen this do you think there are other</p> <p>2 consultants that had that position?</p> <p>3 A. These were notes for myself. Lying to myself would be</p> <p>4 difficult. Yes, I do think so, yes. I think that Lee and</p> <p>5 Faich, several of us wanted that section to be added.</p> <p>6 Q. Okay.</p> <p>7 A. But again, this is 10 years ago and -- but I wanted to write</p> <p>8 this down for this very reason.</p> <p>9 Q. Okay. And then the "other" that you're referring to there,</p> <p>10 are those Pharmacia and Pfizer employees?</p> <p>11 A. I would think so.</p> <p>12 Q. And do you recall who any of those were?</p> <p>13 A. No, but I remember Geis said, Yes, we want to put it in,</p> <p>14 because that's how he responded to me. And then I don't know</p> <p>15 about Verburg and Lefkowitz because I never corresponded with</p> <p>16 them directly about it back then.</p> <p>17 Q. Okay. Would you look at the last page of <u>Exhibit 211</u>, Bates</p> <p>18 number ending 127.</p> <p>19 A. Yes.</p> <p>20 Q. Do you see at the top near the top of the page it says, "Try</p> <p>21 to" -- something?</p> <p>22 A. Yes.</p> <p>23 Q. Could you read that section --</p> <p>24 A. Sure.</p> <p>25 Q. -- through the cross hatching a little below it?</p>	<p style="text-align: right;">224</p> <p>1 (Exhibit No. 212 marked</p> <p>2 for identification.)</p> <p>3 THE WITNESS: Okay.</p> <p>4 Q. (BY MR. MONTGOMERY) Is <u>Exhibit 212</u> another set of notes by</p> <p>5 you?</p> <p>6 A. Yes, it is.</p> <p>7 Q. And do you know what prompted you to write these notes?</p> <p>8 A. No, I don't.</p> <p>9 Q. Okay. Do you see maybe a quarter of the way down the page on</p> <p>10 the first page it starts, "We should"?</p> <p>11 A. Yes.</p> <p>12 Q. Could you read that through the end of the page, please.</p> <p>13 A. Yes. "We should have let the reader and the editor know what</p> <p>14 our process was. We were so focused on aspirin symptoms, et</p> <p>15 cetera, et cetera, the issue of six months versus 12 months</p> <p>16 got lost, was our fault. FS and others didn't see the need</p> <p>17 to not only present the six months but also why not the</p> <p>18 12 months. There was no data hidden as two to three months</p> <p>19 later everything was discussed at the FDA. We were all proud</p> <p>20 of the JAMA paper. We didn't see the six and 12-month</p> <p>21 clearly or we would have shared with the reader and the</p> <p>22 editor. Why not? Nothing was hidden. The FDA session had</p> <p>23 both. What reason" -- I can't read that word -- "to hide it.</p> <p>24 It wasn't hidden. But we didn't appreciate the importance of</p> <p>25 sharing not just Y6 but also 12."</p>



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<p>225</p> <p>1 Q. All right. And when you said FS, do you mean yourself?</p> <p>2 A. I don't remember where I said FS.</p> <p>3 Q. Okay. It should be right after "our fault" towards the top.</p> <p>4 A. Let me look. Yes, me. I and others didn't see the need to</p> <p>5 not only present the six-month, but why not the 12-month. I</p> <p>6 think this was -- I think this was around the response to the</p> <p>7 letters to the editor of JAMA.</p> <p>8 Q. Okay. Didn't you in fact see the need to explain --</p> <p>9 A. I did.</p> <p>10 Q. -- that? So --</p> <p>11 A. Yeah, I don't think --</p> <p>12 Q. Let me ask the question and then you can answer it.</p> <p>13 A. Okay.</p> <p>14 Q. I mean I know it's just a note, but is that statement</p> <p>15 regarding yourself and others accurate do you think regarding</p> <p>16 your thoughts when you were working on the JAMA article?</p> <p>17 A. You know, I think it was. I think that we didn't focus on</p> <p>18 the importance of that. And I think this was in preparation</p> <p>19 for the response because it has on the second page, We</p> <p>20 acknowledge that, "in retrospect we would have avoided</p> <p>21 confusion by explaining why we chose to prevent the six-month</p> <p>22 analysis."</p> <p>23 So in other words the providence of this I believe is</p> <p>24 when I was starting to think and making notes about how we</p> <p>25 would describe what happened, I don't remember how much of</p>	<p>227</p> <p>1 wanted him to put in a section about the fact that the study</p> <p>2 went longer than six months and why we limited the data to</p> <p>3 six months, it wasn't limited to just to informative</p> <p>4 censoring. And my understanding was that he told</p> <p>5 Dr. Lefkowitz and then I don't know what happened.</p> <p>6 Q. So do you actually know personally why it is that</p> <p>7 Dr. Lefkowitz didn't put in that information in the JAMA</p> <p>8 manuscript?</p> <p>9 A. No. And furthermore, I don't know that that's true. In</p> <p>10 other words, you implied that he didn't put it in the JAMA</p> <p>11 manuscript. Well, it's possible that he wrote it and he was</p> <p>12 ready to send it and, boom, in the same afternoon here</p> <p>13 arrives your reprints of the paper. So the part about the</p> <p>14 fast communication is literally, they were moving very fast,</p> <p>15 and you've seen it five or six times in my notes. Like here,</p> <p>16 "JAMA fast track," it went fast. It moved very fast. So I</p> <p>17 don't know that Jim decided not to do it. He may well have</p> <p>18 decided to do it, but then boom, the thing arrived. It was</p> <p>19 unpredictable. The author has no control over when the thing</p> <p>20 is going to see the light of day.</p> <p>21 Q. Okay. But you don't know either way how it is after you told</p> <p>22 Dr. Geis that you wanted the section in that it didn't get</p> <p>23 in?</p> <p>24 A. Correct.</p> <p>25 MR. MONTGOMERY: That's all I have for</p>
<p>226</p> <p>1 this got into our actual response, but that we didn't -- we</p> <p>2 didn't focus on the importance of that. The data after 12 --</p> <p>3 after six months. We didn't hide anything because we're not</p> <p>4 that crazy. I mean three months later every bit of</p> <p>5 information is going to be aired in the most public of public</p> <p>6 presentations, but we were so focused on the 500 other moving</p> <p>7 parts of the study that the issue of the six months versus</p> <p>8 the 12 months got relatively lost. And that's what I'm</p> <p>9 saying that we -- it would have been better if we had.</p> <p>10 Now, I did want to. I told you. What I told was</p> <p>11 accurate that I called Geis and said, We got to get that in.</p> <p>12 But I think this is addressing more how did it happen. And</p> <p>13 we were so focused on the other 750 moving parts that the</p> <p>14 12-month -- the six- and 12-month issue got lost.</p> <p>15 Relatively.</p> <p>16 Q. But it's your understanding -- well, strike that.</p> <p>17 You told Dr. Geis that you wanted a section concerning</p> <p>18 informative censoring in the paper; is that right?</p> <p>19 A. Absolutely.</p> <p>20 MR. WEISS: Object to the form of the</p> <p>21 question.</p> <p>22 Q. (BY MR. MONTGOMERY) Okay. And it's your understanding that</p> <p>23 he then told Dr. Lefkowitz to put that section in the paper;</p> <p>24 is that right?</p> <p>25 A. Well, I can't say it was about informative censoring. I</p>	<p>228</p> <p>1 now. Do you want to go off the record for a few minutes?</p> <p>2 MR. WEISS: Yeah, let's go off the record</p> <p>3 for a few minutes.</p> <p>4 THE VIDEOGRAPHER: We are going off the</p> <p>5 record. The time is 4:15 p.m.</p> <p>6 (Recess 4:15-4:24.)</p> <p>7 THE VIDEOGRAPHER: We are back on the</p> <p>8 record. The time is 4:24 p.m. This is the beginning of Tape</p> <p>9 No. 6.</p> <p>10</p> <p>11 EXAMINATION</p> <p>12 BY MR. WEISS:</p> <p>13 Q. Good afternoon, Dr. Silverstein. Can I ask you to pick up</p> <p>14 Exhibit 211 which is part of your handwritten notes?</p> <p>15 A. I have it.</p> <p>16 Q. Okay. I'll ask you to turn to the second page of that</p> <p>17 document which ends in the Bates Nos. 125.</p> <p>18 A. I have that.</p> <p>19 Q. And I will ask you to take a look at about the bottom third</p> <p>20 of the page there's a No. 6. Do you see that?</p> <p>21 A. I do.</p> <p>22 Q. Okay. And could you read that section into the record,</p> <p>23 please.</p> <p>24 A. It's actually I think a G and it says --</p> <p>25 Q. Oh, thank you.</p>



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<p style="text-align: right;">229</p> <p>1 A. Okay. The decision was made by the entire team to focus on 2 the first six months. The paper was written by the entire 3 team. Each consultant stated that -- each consultant 4 stated -- had made a statement about the conflict of interest 5 statement. No consultant had any reason to mislead the 6 readers about the results. The results were the same at six 7 months and the entire study, six months and the entire study. 8 Several consultants and others wanted to add a section 9 regarding the timing of the first six months. The fact that 10 it was a rapid track, some confusion led to not including 11 this section. 12 Q. Okay. And the section that you just read, which is I guess 13 G, then you have H, I, and then there appears to be -- 14 A. A J and a K. 15 Q. J, there we go, thank you. And I think you just read, "No 16 consultant had any reason to mislead readers about the 17 results." 18 Do you still believe that's true? 19 A. Absolutely. 20 Q. Okay. With respect to the employees of Searle and/or 21 Pharmacia who were co-authors of the JAMA article, do you 22 believe that they had any reason to mislead readers about the 23 results? 24 MR. MONTGOMERY: Objection to form. 25 THE WITNESS: No, I have no reason to</p>	<p style="text-align: right;">231</p> <p>1 sitting in the side section at the FDA aside from the FDA 2 panel itself. 3 How could anybody say data was intentionally hidden 4 when four months later with an open forum, press, 5 competitors, et cetera, all to be discussed. 6 So we didn't want to hide -- nobody wanted to hide the 7 data and not wanted to have actions misinterpreted since the 8 data was soon to go public. It makes no sense. 9 Q. Okay. Thank you. Do you have an understanding of when -- 10 well, strike that. 11 The advisory committee took place in February, correct? 12 A. Correct. 13 Q. And do you have an understanding of when the SNDA in 14 connection with that advisory committee hearing was submitted 15 to the FDA? 16 A. Well, as far as I understand it, it was almost a year before. 17 It was in the year 2000, in March or something of 2000. I 18 don't know exactly. 19 Q. Do you have an understanding of the relationship between the 20 timing of the submission of the SNDA and the submission of 21 the JAMA manuscript to JAMA? 22 A. I think the SNDA was submitted to the FDA first and then the 23 manuscript went to JAMA. I think. 24 Q. And do you have an understanding of the extent of the data 25 that was contained in the SNDA that was submitted to the FDA?</p>
<p style="text-align: right;">230</p> <p>1 believe that. I knew them. As you heard me say, I had 2 worked with Steve Geis for 14 years and held him in the 3 highest esteem as a clinical investigator who was probably -- 4 is probably one of the best clinical investigators I've ever 5 met. And I was -- never even crossed my mind that there 6 would be any manipulation of any part of this nor did anybody 7 at any point tell me that something like that was necessary. 8 Q. (BY MR. WEISS) And after all that has transpired in the 9 aftermath of the publication of the JAMA article, has that 10 changed your opinion of Dr. Geis? 11 A. No. 12 MR. MONTGOMERY: Objection to form. 13 THE WITNESS: No, it hasn't. 14 Q. (BY MR. WEISS) I think you testified earlier about the extent 15 to which you trusted Dr. Geis. Do you recall that testimony? 16 A. I do. 17 Q. And do you still trust him to the same extent today? 18 A. I do. 19 Q. I'll ask you to turn to the next page of <u>Exhibit 211</u> and it 20 is Bates No. 00126, and could you read the top of that page 21 through about two-thirds of the way down. 22 A. Yes. "The feeling was we were off to the FDA in three months 23 and all the data would be presented in open forum. People 24 who wrote the paper also were involved in the FDA panel." 25 And in fact I think almost all the authors were there</p>	<p style="text-align: right;">232</p> <p>1 A. Yeah, and I read it when Matt showed me the full text, 2 180,000 pages. I mean this was a humongous deposit of 3 information. 4 Q. And -- but in terms of the length of the data that was 5 submitted six months or 12 months, do you have an 6 understanding of what the SNDA contained in that regard? 7 A. 12 months. It may have dealt with the issue about why they 8 thought six months was more valid because six months was the 9 way you would make the point that it seemed like this is 10 tracking on all the other studies that were done. You know, 11 we flashed by several of these presentations, but in it 12 you'll see the other NSAIDs causing complications, causing 13 ulcers, et cetera. That's all the data I was talking about, 14 I've been talking about all day, and the six-month data 15 really confirmed -- conformed much more closely to that, 16 especially -- especially if you include symptomatic ulcers. 17 So I think -- I don't know, I never read the whole NDA, 18 but I assumed they declared all the data and said, Look, we 19 want to focus on the first six months and I think Goldkind 20 came back and said, No, no, I don't want to do that, I want 21 to look at all the data. 22 Q. Okay. I'd like you to take a look at <u>Exhibit 202</u> which is a 23 cover e-mail with slides that were presented by you at ACP. 24 A. Is this -- this? 25 Q. Yes.</p>



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<p style="text-align: right;">233</p> <p>1 A. I don't have the e-mail here anymore. I have the slides.  2 Q. That's fine, I'm not going to ask you about the e-mail.  3 Before we dive into the document I think you testified  4 earlier in sum and in substance that you discussed with  5 representatives of Searle or Pharmacia that in connection  6 with your presentation you would explain the fact that the  7 study went longer than six months but for certain reasons you  8 decided to only look at six months of data.  9 Is that an accurate statement of your earlier  10 testimony?  11 A. It is, and I discussed it with Steve Geis and I don't  12 remember -- and Steve I think discussed it with Phil  13 Needleman who really was the spiritual head and literal head  14 of this whole effort. And it was -- I said, I want to do  15 this, and Phil came by and he suggested that one way to  16 phrase it would be, The study lasted longer than six months  17 but the data after six months was very difficult to interpret  18 and therefore we decided to focus on the first six months of  19 this presentation.  20 Q. Was there any resistance on the part of either Dr. Geis or  21 Dr. Needleman to your presentation of those facts?  22 A. There was none.  23 Q. At any point in time did any representative of Searle or  24 Pharmacia discourage you or attempt to prohibit you from  25 disclosing the extent of the data or the results of the CLASS</p>	<p style="text-align: right;">235</p> <p>1 consider to be an upper GI ulcer complication? And that this  2 was designed prospectively. It would be totally invalid if  3 we tried to design it in retrospect because then you could  4 say, C'mon, you know, you talked about the hematocrit being  5 seven percent points down after you looked at the data. That  6 didn't happen.  7 This was all designed prospectively with the input of  8 me as an experienced clinical gastroenterologist and all the  9 other stuff you were forced to listen to about what I've done  10 over the last 30 years, and the other gastroenterologists.  11 Because in fact there is a great group of gastroenterologists  12 on this study. Jay Goldstein. Naurang Agrawal is one of the  13 nicest people in the whole world. And we all put input.  14 Because it was this question of, What is significant? And I  15 know for you folks it might be, Well, c'mon, is it GI? No,  16 it's not that way, trust me. It's very complicated to say  17 whether something is a significant bleed or not. And you  18 don't want to include something that's not significant but  19 equally you don't want to exclude something that is  20 significant. And so that's why we said it's got to be a  21 certain change in the hematocrit, a certain change in pulse  22 rate, a certain change in blood pressure to define that the  23 person was having a significant bleed. This is one of the  24 most important parts of these studies and I believe that  25 every clinical trial that does it has to do that.</p>
<p style="text-align: right;">234</p> <p>1 study?  2 A. They did not.  3 Q. I'm going to ask you to take a look, going back to  4 Exhibit 202, at Side No. 12.  5 A. (Witness complies.) Okay.  6 Q. And I'll ask you to take a look under the heading Design, the  7 second bullet says, "Minimum six months exposure."  8 Do you see that?  9 A. Yes.  10 Q. What would that -- well, strike that.  11 Would that indicate anything to somebody seeing this  12 presentation as to the extent of the data from the CLASS  13 trial?  14 MR. MONTGOMERY: Objection to form.  15 THE WITNESS: In fact, it would suggest  16 that the trial went longer than six months, and now that I'm  17 looking at that slide, I remember -- with the caveat of a  18 68-year-old brain thinking about something that happened  19 10 years ago -- that I may have said something like, you  20 know, that's what I said when I started that it was -- it  21 went longer than six months but we're focused on the six  22 months.  23 Q. (BY MR. WEISS) I'll ask you to take a look at Slide 14 and if  24 you could tell me what it is this Slide 14 describes.  25 A. So this is talking about the primary end point, What do we</p>	<p style="text-align: right;">236</p> <p>1 Q. Was this primary end point as described in Slide 14 the same  2 primary end point that is described in the study protocol?  3 A. Yes, I believe so.  4 Q. I'll ask you to take a look at Slide 20.  5 A. Okay.  6 Q. And I'll ask you to take a look at the first set of bar  7 graphs which are labeled Complications. Do you see that?  8 A. I do.  9 Q. What does that reflect?  10 A. What it said was that -- I'm color-blind but in this  11 particular instance I don't think there are any colors here.  12 These are vacant bars, a pet peeve of mine. But anyway, it  13 says that when you looked at complications which I defined  14 earlier, that there were about .7 percent complications on  15 the celecoxib and about 1.4 percent complications on the  16 comparator NSAIDs, but that was not statistically  17 significantly different.  18 And here you get into a whole consideration of, What do  19 you mean by statistically significantly different? And it is  20 not so easy. You know, if you want to be sure, make it .01,  21 but .01 maybe you need 16,000 patients. If you want to make  22 it .1 instead of .05, maybe you can get by with 2,000  23 patients, but it means that one time in 10 you're going to  24 draw a conclusion that something's significant and it's not.  25 That's the whole nature. I shouldn't lecture about</p>



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<p style="text-align: right;">237</p> <p>1 statistics as I told you several times today, but it's not</p> <p>2 that easy. And it could be one or two more patients and it</p> <p>3 wouldn't have been .09. I never did that calculation because</p> <p>4 nobody wants to hear that. It's the kind of thing people</p> <p>5 don't like to listen to. Yeah, right. But if it were one or</p> <p>6 two more patients it might have been .04. That's the problem</p> <p>7 with an event that's so rare.</p> <p>8 Q. Okay. Could you turn to Slide 33?</p> <p>9 A. (Witness complies.)</p> <p>10 Q. And I'll ask you to take a look at the middle column which is</p> <p>11 diclofenac and the last line of the -- the last row reads</p> <p>12 withdrawals and there is a number there, 16.6 with a star</p> <p>13 next to it. Do you see that?</p> <p>14 A. I do.</p> <p>15 Q. What does that reflect?</p> <p>16 A. That means that there were significantly -- at a .05 P value</p> <p>17 significantly more withdrawals for the diclofenac group than</p> <p>18 from the celecoxib group.</p> <p>19 Q. Is that fact related to the informative censoring theory?</p> <p>20 A. I think it is.</p> <p>21 Q. And in presenting this slide was there any discussion about</p> <p>22 this withdrawal rate influencing or impacting the study</p> <p>23 results?</p> <p>24 A. I don't remember. That's a fair question. In other words,</p> <p>25 when I -- this is -- what we're looking at, this is my</p>	<p style="text-align: right;">239</p> <p>1 of it.</p> <p>2 Q. I'm going to ask you to go back to Slide 31.</p> <p>3 A. (Witness complies.)</p> <p>4 Q. And at the bottom of the slide above the line, the P value of</p> <p>5 0.05, it says, "versus celecoxib/median exposure nine</p> <p>6 months."</p> <p>7 Do you see that?</p> <p>8 A. I do.</p> <p>9 Q. Would that indicate anything to somebody seeing or listening</p> <p>10 to this presentation about the extent of the data from the</p> <p>11 CLASS study?</p> <p>12 MR. MONTGOMERY: Object to form.</p> <p>13 THE WITNESS: I think it would. I mean I</p> <p>14 think it suggests that this wasn't a six-month study, it went</p> <p>15 longer, which is consistent with what I clearly said at the</p> <p>16 beginning of the presentation. And there was no attempt to</p> <p>17 hide anything. I mean there it was.</p> <p>18 Q. (BY MR. WEISS) And then when you were discussing these slides</p> <p>19 with Mr. Montgomery earlier there was some discussion about</p> <p>20 who prepared these slides or this slide in particular. Do</p> <p>21 you recall that?</p> <p>22 A. Yes. It was prepared by -- by the company, because I didn't</p> <p>23 have the data to do it; however, the talk -- and already it's</p> <p>24 probably enough to make you sick to your stomach -- the talk</p> <p>25 you can see is my talk because this is the stuff that I</p>
<p style="text-align: right;">238</p> <p>1 presentation that I made to the ACP, right?</p> <p>2 Q. Yes.</p> <p>3 A. So the question is when I said that -- you know, I don't</p> <p>4 remember. It would have been a logical place to say, Hey,</p> <p>5 this is part of what confused it, but I don't remember if I</p> <p>6 said it or not.</p> <p>7 Q. And the star -- I'm sorry if you said this already, but the</p> <p>8 star next to the 16.6 indicates what?</p> <p>9 A. That the P value is less than or equal to .05 versus</p> <p>10 celecoxib.</p> <p>11 Q. So that the difference in the withdrawals between the two</p> <p>12 groups --</p> <p>13 A. Were clinical -- were statistically significant.</p> <p>14 Q. Now --</p> <p>15 A. You know, just if I may, one comment?</p> <p>16 Q. Sure.</p> <p>17 A. Joan actually clarified my thinking about some of this. What</p> <p>18 we went through was, What happened? You know, what happened?</p> <p>19 And it was that's what happened. You know, we were looking</p> <p>20 at the data and saying, you know, it went along just the way</p> <p>21 we would have sort of predicted it would go and then it got</p> <p>22 funny and that's when the fact that so many more people had</p> <p>23 withdrawn from the diclofenac group, it was like that looks</p> <p>24 like something is changing in that group. And that was the</p> <p>25 genesis of the consideration of informative censoring or part</p>	<p style="text-align: right;">240</p> <p>1 felt -- you know, my slides are -- I'm a very, very, very</p> <p>2 experienced lecturer and my slides look like that. I mean</p> <p>3 they look like that. They don't have -- they're not covered</p> <p>4 with data the way some people are where you have to sit back</p> <p>5 and go, Oh, crap, is this person going to read them? Are</p> <p>6 they going to look at them? Am I going to read them? Mine</p> <p>7 are straightforward. This is the presentation that I worked</p> <p>8 on for years with how to look at this. So here's the data</p> <p>9 about also complications with NSAIDs, and then the COX-2,</p> <p>10 some of the data that it's better than Naproxen, et cetera.</p> <p>11 Q. But prior to presenting these slides you reviewed them?</p> <p>12 A. I believe I did.</p> <p>13 Q. And you approved --</p> <p>14 A. Yes.</p> <p>15 Q. -- using them?</p> <p>16 A. I did.</p> <p>17 Q. I think we can put 202 away.</p> <p>18 I'd like you to take a look at Exhibit 199 which is the</p> <p>19 e-mail containing the pink sheet article.</p> <p>20 A. Okay. Okay.</p> <p>21 Q. And Mr. Montgomery pointed you to a paragraph at the bottom</p> <p>22 of the page which begins, "Data from the first six months of</p> <p>23 the trial were used for the head-to-head comparison of</p> <p>24 NSAIDs," et cetera, et cetera.</p> <p>25 And I think your testimony was you weren't sure whether</p>



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<p style="text-align: right;">241</p> <p>1 or not that was something that you specifically -- well,</p> <p>2 strike that.</p> <p>3 I think you said that you don't recall whether what is</p> <p>4 reflected here was something you actually said; is that fair?</p> <p>5 A. That is correct.</p> <p>6 Q. Okay. Now, notwithstanding whether or not you used these</p> <p>7 actual words that are here in this article, is what is</p> <p>8 reflected here about the use of the first six months of data</p> <p>9 from the trial for analysis consistent with your recollection</p> <p>10 of the presentation that you gave?</p> <p>11 A. So, I'm sorry. You're saying that this came after I</p> <p>12 presented to the ACP?</p> <p>13 Q. Well, let's just take a step back. Do you see up at the top</p> <p>14 that this is dated April 24, 2000?</p> <p>15 A. Right, right.</p> <p>16 Q. Okay. And do you recall that the presentation that was at</p> <p>17 ACP took place on or about April 15th or --</p> <p>18 A. Okay.</p> <p>19 Q. Okay. So does that suggest to you that this came out -- that</p> <p>20 this article was published after your presentation?</p> <p>21 A. Yes.</p> <p>22 Q. And does it suggest to you that this article was informed by</p> <p>23 your presentation?</p> <p>24 A. This article was informed -- yes, I would think so.</p> <p>25 Q. Okay. Now, again looking at this paragraph which reads,</p>	<p style="text-align: right;">243</p> <p>1 A. It's as if I felt like there was three reasons and here's one</p> <p>2 of them and then the person didn't put the other two down, if</p> <p>3 I said that.</p> <p>4 Q. Okay. Now, I'd like you to take a look at the JAMA article</p> <p>5 which has previously been marked as Wolfe Exhibit 3.</p> <p>6 A. I don't know where that is. I've got the editorial. I got</p> <p>7 it. Okay. Here we are.</p> <p>8 Q. And so, Dr. Silverstein, in your view is there anything in</p> <p>9 the JAMA article which discloses the fact that there is more</p> <p>10 than 13 months of data from the CLASS study -- I'm sorry.</p> <p>11 Strike that.</p> <p>12 In your review is there anything in the JAMA article</p> <p>13 which reflects the fact that there's more than six months of</p> <p>14 data from the CLASS study?</p> <p>15 A. Yeah. I mean in the study protocol it says, "Patients were</p> <p>16 provided an opportunity to complete a minimum of six months</p> <p>17 of treatment but could go longer than that."</p> <p>18 Q. Okay.</p> <p>19 A. And I think it says four, 13 and 26 weeks, which would be six</p> <p>20 months, right? Half a year. And then every 13 weeks</p> <p>21 thereafter, also addressing the fact that the study went</p> <p>22 longer than six months.</p> <p>23 Q. Okay. Are you referring to --</p> <p>24 A. I'm sorry.</p> <p>25 Q. -- Bates No. 78879 under the heading in the column of the</p>
<p style="text-align: right;">242</p> <p>1 "Data from the first six months of the trial were used for</p> <p>2 the head-to-head comparison of NSAIDs," my question is: Even</p> <p>3 assuming that you didn't use those exact words in your</p> <p>4 presentation, is what is reflected here consistent with your</p> <p>5 recollection of what you said in substance about the use of</p> <p>6 six months of data?</p> <p>7 MR. MONTGOMERY: Object to form.</p> <p>8 THE WITNESS: It is possible that I said</p> <p>9 that but not -- but not only that. That's the part, you</p> <p>10 know -- I might have said everybody had to be on this -- the</p> <p>11 drugs for six months, therefore six months was a reasonable</p> <p>12 place to do an analysis. But I -- you know, this is a</p> <p>13 summary of what I said, it's not a quote. And I would assume</p> <p>14 I said there were other factors that led us to believe that</p> <p>15 the six-month was better data than the data after six months,</p> <p>16 including informed.</p> <p>17 Q. (BY MR. WEISS) Let's just focus on the first part of the</p> <p>18 sentence which states that, "Data from the first six months</p> <p>19 of the trial were used for the head-to-head comparison of</p> <p>20 NSAIDs."</p> <p>21 A. Okay.</p> <p>22 Q. Is that consistent with your recollection of what you said in</p> <p>23 substance in your presentation?</p> <p>24 A. Yes, it's just not -- I'm sorry; it's just not complete.</p> <p>25 Q. Okay. No, that's fair.</p>	<p style="text-align: right;">244</p> <p>1 middle of the page labeled Study Protocol?</p> <p>2 A. Yes.</p> <p>3 Q. And that reads, "After baseline visit, follow up clinic</p> <p>4 visits took place at Weeks 4, 13 and 26 after the initial</p> <p>5 dose of medication and every 13 weeks thereafter?"</p> <p>6 That's what you were referring to?</p> <p>7 A. That's correct. And then it says patients were provided an</p> <p>8 opportunity to complete a minimum of six weeks of</p> <p>9 treatment -- six months.</p> <p>10 Q. Now, based on various of the things that we've just looked</p> <p>11 at, is it your belief or understanding that at the time that</p> <p>12 the JAMA article was submitted for publication, the fact that</p> <p>13 there was more than six months of data from the CLASS trial</p> <p>14 had been publicly disclosed?</p> <p>15 MR. MONTGOMERY: Object to form.</p> <p>16 THE WITNESS: Well, it certainly had</p> <p>17 been -- it certainly had been submitted to the FDA so the FDA</p> <p>18 knew about that. I don't -- can you tell me when the article</p> <p>19 was submitted, when the manuscript was submitted?</p> <p>20 Q. (BY MR. WEISS) I'll represent to you it was submitted in mid</p> <p>21 June of 2000.</p> <p>22 A. So it was a month or two after my ACP presentation where I</p> <p>23 said it?</p> <p>24 Q. That's my understanding.</p> <p>25 A. And so I guess -- I guess it was what I said at the American</p>



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<p style="text-align: right;">245</p> <p>1 College of Physicians that the study went longer, so to that 2 audience I said that the study went longer than six months. 3 The FDA knew it went longer than six months. I don't know 4 other potential venues where that would have come up. 5 Q. Well, was there -- to your knowledge was there news coverage 6 of the presentation at the American College of Physicians? 7 MR. MONTGOMERY: Object to form. 8 THE WITNESS: I gathered that that's what 9 we were looking at with the pink slips or the pink sheet or 10 whatever it is, slips. 11 Q. (BY MR. WEISS) Did the fact that the -- did the fact that 12 there was more than six months of data -- well, strike that. 13 Did the fact that that more than six months of data was 14 available from the CLASS -- well, strike that. That's a 15 difficult question to ask. It's much easier to lead them 16 but -- 17 Did the fact that it was publicly disclosed that more 18 than six months of data was available from the CLASS study -- 19 well, strike that. I'm going to have to formulate that 20 better. I'll move on and come back to it. 21 Earlier there was some discussion and some testimony 22 about your view that you would have preferred that the JAMA 23 article included a section discussing the six-month issue; is 24 that accurate? 25 A. Yes, it is.</p>	<p style="text-align: right;">247</p> <p>1 A. I do. 2 Q. Okay. And notwithstanding that testimony, did you fully 3 understand the basis for the decision to publish only six 4 months of data way back in June of 2000? 5 A. Yes, I think so. 6 Q. Do you have -- do you understand that in this lawsuit the 7 plaintiffs are alleging that the defendants defrauded the 8 investing public? 9 A. That's what I understand. 10 Q. And do you understand that they claim that part of that fraud 11 was the JAMA article of which you were the primary author? 12 A. I do. 13 Q. Do you have any reaction to those allegations? 14 A. Well, maybe two parts. One is would I have done that and the 15 answer is absolutely no, not, never would I have done that. 16 There was no reason for me to do it. It made no sense at all 17 why I would be involved in defrauding anybody. I have never 18 owned a stock -- a share rather of Pfizer, Pharmacia or 19 Searle. I don't know even know if they still exist or are 20 they all part of Pfizer? Literally. If I have a mutual 21 fund, which I have two, which has 2700 companies, perhaps one 22 is Pfizer. I never looked at that. 23 I never looked at the Pfizer share price. I don't know 24 what happened to the Pfizer share price. You know, with this 25 kerfuffle, you know, that is the basis of the lawsuit. So</p>
<p style="text-align: right;">246</p> <p>1 Q. Now, when the article came out and was published and you saw 2 it for the first time, as you testified, that that section 3 didn't make it into the final version of the article, you 4 didn't make any attempt to retract the article or correct the 5 article at that point in time? 6 A. I did not. 7 Q. Okay. Was that due in part to your understanding that the 8 existence of more than six months of data had been publicly 9 disclosed prior to the submission of the JAMA article to 10 JAMA? 11 MR. MONTGOMERY: Object to form. 12 THE WITNESS: To JAMA? 13 Q. (BY MR. WEISS) Yes. 14 A. Yes. At least it appeared from what I was told that the 15 JAMA -- one of the JAMA editors knew that there was more data 16 and didn't say, Wait a second, hold it, let's hold 17 publication until we clarify this issue. So it was one of 18 the factors that the FDA having said publicly at the ACP that 19 the study went for longer than six months, the fact that I 20 still thought that the six-month data was the better data 21 were the factors I guess that went through my mind. 22 Q. Now, I think you testified earlier that you don't have a 23 complete understanding of the term "informative censoring" or 24 that you're not all that comfortable with it. Do you recall 25 that?</p>	<p style="text-align: right;">248</p> <p>1 from a personal standpoint I just had absolutely no reason to 2 do that. It just -- and that's what I told Cathy DeAngeles 3 and she said, Yeah, why would you do that? And second of 4 all, the second part was asking me if anybody from the 5 company -- and what were you asking about that? 6 Q. Well, I guess the same question with respect to the company 7 authors, which is -- you said you had two reactions? 8 A. Yes. That was to that. But first I wanted to deal with 9 whether I would do it. The second reaction is whether they 10 would do it and I had absolutely no indication that they 11 would do that. Not from Needleman, who is respected as a 12 first class scientist, you know, I won't even -- well, maybe 13 I will. I mean the talk was he's going to win a Nobel prize 14 for this COX-2 stuff. I mean that's what the talk was, not 15 that something was going on that would be embarrassing. 16 Geis is a first rate clinical investigator. Verburg is 17 a smart, good investigator. Jim Lefkowitz was a great 18 investigator. Aimee Burr, I mean that whole group, and I 19 never once saw any indication that anybody was attempting to 20 manipulate stock prices or anything like that. I -- I had no 21 experience seeing that at all, ever. 22 Q. Have you read the editorial that was published in the British 23 Medical Journal in June of 2002 by Peter Juni, Paul Dieppe 24 and Anne Rutjes? 25 A. Uh-huh. (Witness nods head up and down.)</p>



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<p style="text-align: right;">249</p> <p>1 Q. And do you have an understanding of the criticisms that they 2 offered of the JAMA article? 3 A. Uh-huh. (Witness nods head up and down.) 4 Q. What do you understand those criticisms to be, generally? 5 A. Well, I got so annoyed when I read it that I don't exactly 6 remember specifically what happened. What I felt was here 7 were two fellows in rheumatology, which means they are two or 8 three years out of medical school, two of them, and this 9 other person that I didn't know at all, going off on dredging 10 data, ethical misconduct. I mean I didn't think there was a 11 basis for any of this. And I don't know anything about Juni, 12 but I was looking after GI bleeders when these two fellows 13 weren't born. Literally. I was taking care of GI bleeders 14 and using lasers and using heater probes in 1972 and I'll bet 15 they were just in the birthing process or were a few years 16 old. And it really bothered me. It didn't bother me back 17 then because I was sort of in the, you know, Here it goes, 18 here's another group. But when I read it recently it was 19 like, I can't believe that they said that. I mean there were 20 no grounds on which to make those accusations. 21 And a metaanalysis? I mean I have done this research 22 with my hands. I am an animal lover and I have sacrificed a 23 lot of animals to try to get real data about what happens to 24 bleeding and how you can stop bleeding. So I'm talking about 25 really being involved in this. I looked at every one of</p>	<p style="text-align: right;">251</p> <p>1 or six times today but I mean what I'm saying. The amount of 2 data and the amount of work that goes into these trials, just 3 the patient effort, just the patients who say, Yes, I'll be 4 willing to go into a placebo control trial, or, I'm willing 5 to take this new medication and have a comparison to these 6 other medications; the amount of work that the patients do is 7 immense. 8 And no, I don't think that the whole study was negated 9 and I think in fact that the study is positive. I think -- I 10 think it's positive and fits into the -- and perhaps I'm 11 guilty of seeing what I think it should be and then seeing 12 that it is that. But I think the data -- you know, you look 13 at these things like this (indicating) and you can say 14 it's .09. Well, maybe if it was this it would be .03. I 15 mean it's -- sometimes just one or two cases will change 16 that. And again, when you're dealing with a problem so 17 big -- this is why I started out today talking about how you 18 could find surrogate markers. It sounded like esoteric 19 nonsense from an academic airhead perhaps, but it's not. It 20 is the essence of how you design these trials. 21 It is extremely difficult -- 8,000 patients, I mean 22 imagine how much effort and cost goes into that. And do you 23 know who's going to pay for it? Nobody's going to pay for it 24 but the pharmaceutical industry, because under any government 25 they're not going to come up with enough money to pay for</p>
<p style="text-align: right;">250</p> <p>1 these complications in the mucosa trial. Every single 2 patient I reviewed, every one to be sure that they 3 adjudicated to be clear. I was very much involved in the 4 adjudication here, and for somebody to sit back and say, This 5 is terrible, you know, these people didn't do a good job at 6 all and what we need is a good metaanalysis which means a 7 gamish of stuff thrown into a pot, you know, none of which is 8 comparable to anything else. So I didn't respond really 9 positively to that. 10 Q. Okay. And earlier when you were talking with Mr. Montgomery 11 about the intentional inclusion of another section in the 12 JAMA article and you said that you thought that you could 13 have avoided some confusion by including that section, do you 14 think that the failure to include that section renders the 15 JAMA article fraudulently misleading? 16 A. No. 17 MR. MONTGOMERY: Object to form. 18 THE WITNESS: You know, I don't think so. 19 As a matter of fact, I think had that section been in there 20 so people would understand how we did it, the article stands 21 on its own. I mean it's a huge amount of data, of 22 interesting data about what happened to these people. And 23 the thought that it was all undone by the exclusion of that 24 paragraph, you know, is enough to make me nauseated. This 25 was a huge -- I mean I -- you know, I know I've said it five</p>	<p style="text-align: right;">252</p> <p>1 these trials. And furthermore, how do you find out, Well, 2 maybe we shouldn't have used that same dose of celecoxib, 3 let's go at a half dose? How are you going to do that? Are 4 you going to go do another 8,000 patient trial? I mean 5 that's the whole reason for doing the surrogate trials where 6 you say, Hey, no ulcer, no complicated ulcer. 7 Now, I mean the FDA -- I told you -- I think the FDA is 8 a great organization and I don't criticize them. I think 9 they have the same problems everybody has, you know, trying 10 to figure out what the best thing to do is. And they toed 11 the line on saying, No, if you want to say there's less 12 bleeding, you prove there's less bleeding. But the 13 problem -- if I were a statistician I could more eloquently 14 explain that when you're dealing with these huge number of 15 patients and the incidence of the event is so small, just a 16 few one way or the other changes -- changes this 17 magical .05 -- which I don't think is magical anyway. 18 You talk to most statisticians and they'll tell you if 19 the difference is significant you don't need P values. Just 20 look at it and you'll say, Yeah, I buy that. It went from .7 21 to 1.5, that's good for me. And a thing with an incidence of 22 one percent, you go from 1.5 to .75, I'll accept that. The 23 more formal people will say, Well, you got to give this .05 24 mathematical consideration of that. Fine. But I know some 25 wonderful statisticians who say if it's really significant</p>



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<p style="text-align: right;">253</p> <p>1 you don't need statistics, you don't need P values. You look 2 at it and it tells you what's happening. 3 I'm not proposing that that's the way this study should 4 have been done. I'm just telling you that it's not simple. 5 And the multiple look issue hasn't come up, you know, where 6 you take multiple looks. You've got to get more stringent in 7 your P value because every time you take a look there's a one 8 in 20 chance that it's going to look significant and it's 9 not. So the next time you look -- every time you look you're 10 increasing the likelihood of a false interpretation. You've 11 got to make the P value more stringent. 12 Q. (BY MR. WEISS) Do you have an understanding in the context of 13 ulcer complications what are sentinel symptoms? 14 A. I have to go back. There are sentinel findings on endoscopy 15 which -- I don't remember how the word "sentinel" was used. 16 I remember I've heard it, it's just like CSUGIEs is one of 17 the words that I've never used. CSUGIEs I don't think helps 18 anybody understand what's going on. And I don't think 19 sentinel symptoms make a lot of sense to me. 20 There are findings at endoscopy, you can look at an 21 ulcer and say, This is a problem ulcer. If the ulcer has a 22 protruding vessel, if it has a clot attached or if it's 23 actively bleeding, the odds of that ulcer being a problem 24 clinically for the patient are much higher than just a single 25 ulcer sitting there. But I don't remember -- you can refresh</p>	<p style="text-align: right;">255</p> <p>1 know, these are signs and symptoms that are much more 2 worrisome. 3 Q. (BY MR. WEISS) Do you have a recollection that in his review 4 Dr. Goldkind suggested that the class data didn't demonstrate 5 a correlation between symptomatic ulcers and ulcer 6 complications because in the cases of ulcer complications 7 where the patients were symptomatic, those symptoms occurred 8 too close in time to discovery of the ulcer complication such 9 that his conclusion was the symptoms were actually the result 10 of the complication, they didn't precede the complication? 11 A. Yeah, I don't remember that -- 12 MR. MONTGOMERY: Object to form. 13 THE WITNESS: -- I don't remember that 14 discussion. 15 MR. WEISS: Okay. I have no further -- 16 THE WITNESS: Not a bad thought but I 17 don't remember that conversation. 18 MR. WEISS: I have no further questions. 19 Thank you very much, Dr. Silverstein. 20 MR. MONTGOMERY: Okay. I just have 21 probably some, three more. 22 23 FURTHER EXAMINATION 24 BY MR. MONTGOMERY: 25 Q. Can you turn to your notes again, <u>Exhibit 211</u>.</p>
<p style="text-align: right;">254</p> <p>1 my memory, I don't remember how people used sentinel 2 symptoms. 3 Q. Sure. Well, in the context of the debate about whether a 4 symptom -- GI adverse -- GI symptoms correlate to ulcer 5 complications, is there some debate around the time period by 6 which symptoms precede an ulcer complication in order to be 7 supportive of that correlation? 8 MR. MONTGOMERY: Object to form. 9 THE WITNESS: Well, the study that I did 10 looked at 30 days before or 24 hours before. 24 hours before 11 when somebody's presenting vomiting blood you can find out 12 what color their stools are. I mean stuff is going on so fast 13 and so furiously, you're trying to save the patient's life. 14 Looking back 30 days when the person is stable, if you can 15 stabilize them, they can answer that question. I think you 16 might say, Are there some symptoms that are worse than 17 others? Oh, clearly there are. I mean it depends on a 18 symptom. Is it a symptom if you vomit blood? Is it a 19 symptom if you have black tarry stools? Is it a symptom if 20 you have penetrating pain here and it goes through to your 21 back? 22 And then there's nausea. Nausea is much less specific. 23 Nausea can occur for a variety of reasons. But somebody 24 vomits blood or somebody has what we call a coffee ground 25 emesis where somebody has black stools or red stools, you</p>	<p style="text-align: right;">256</p> <p>1 A. Okay. (Witness complies.) Yes. 2 Q. On the second page of <u>Exhibit 211</u> -- 3 A. Right. 4 Q. -- which is Silverstein 00125 Bates No. 5 A. Yes. 6 Q. Do you see Item K at the bottom there? 7 A. Yes. 8 Q. And it talks about consultants in that note, do you recall 9 that? 10 A. Yes. 11 Q. And do you understand the consultants there to be your 12 co-authors on the JAMA paper who were not employees of 13 Pharmacia? 14 A. Correct. 15 Q. Okay. Would you look at Exhibit 67 again. That's the press 16 release dated April 17th, 2000. 17 A. Press release. This one? 18 Q. Yes. 19 A. Okay. 20 Q. When we were -- when I had you read through that press 21 release earlier did you make some handwritten notes on the -- 22 A. I did. 23 Q. Are there any handwritten notes on there other than the ones 24 you made? 25 A. No, I just went through and circled a couple of things and</p>



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Fred Silverstein

September 29, 2010

<p style="text-align: right;">257</p> <p>1 there are no handwritten notes.</p> <p>2 Q. Can I take a look at what you wrote down?</p> <p>3 A. Let me look first.</p> <p>4 Q. Sure.</p> <p>5 A. (Witness reviewing document.) Yes.</p> <p>6 Q. Okay.</p> <p>7 MR. MONTGOMERY: Josh, do you want to</p> <p>8 look at it?</p> <p>9 MR. WEISS: No.</p> <p>10 Q. (BY MR. MONTGOMERY) Okay. Do you recall your discussion with</p> <p>11 Mr. Weiss about the BMJ editorial?</p> <p>12 A. Uh-huh.</p> <p>13 Q. You have to respond.</p> <p>14 A. Yes.</p> <p>15 Q. And I take it that you -- from your discussion that you were</p> <p>16 not entirely pleased with the content of that editorial?</p> <p>17 A. That's correct.</p> <p>18 Q. And did you read it at the time that it came out?</p> <p>19 A. I don't remember.</p> <p>20 Q. Okay. Did you write any public response to that editorial?</p> <p>21 A. I did not.</p> <p>22 Q. And why not?</p> <p>23 A. Well, two possibilities: One is -- three -- that I didn't</p> <p>24 read it and there was so much flying around that I just, you</p> <p>25 know, it was just another set of comments. I did read some</p>	<p style="text-align: right;">259</p> <p>1 THE VIDEOGRAPHER: Going off the record.</p> <p>2 The time is 5:09 p.m. This is the end of Tape No. 6.</p> <p>3 (Signature reserved.)</p> <p>4 (Deposition concluded at 5:09 p.m.)</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
<p style="text-align: right;">258</p> <p>1 of the lay press and I read some of the other medical</p> <p>2 comments. I don't remember that -- this one specifically.</p> <p>3 And why not? There's a certain degree of when you're playing</p> <p>4 in the mud, you know, you're going to get covered with mud</p> <p>5 too. I don't operate by insulting somebody. I did here</p> <p>6 but -- and I apologize, but I don't operate in that kind</p> <p>7 of -- you know, I might fantasize about giving him a call and</p> <p>8 saying, Hey, you know, what was the basis of this? And, Was</p> <p>9 that really fair? And, you know, Should you retract that</p> <p>10 because that's -- but I didn't do it. That isn't the way I</p> <p>11 operate, Matt.</p> <p>12 Q. Okay.</p> <p>13 MR. MONTGOMERY: Let's go off the record.</p> <p>14 THE VIDEOGRAPHER: We are going off the</p> <p>15 record. The time is 5:07 p.m.</p> <p>16 (Recess 5:07-5:09.)</p> <p>17 THE VIDEOGRAPHER: Okay. We are back on</p> <p>18 the record. The time is 5:09 p.m.</p> <p>19 MR. MONTGOMERY: Dr. Silverstein, I don't</p> <p>20 have any further questions for you. I'd like to thank you</p> <p>21 for appearing here today. Thank you for your time and your</p> <p>22 candor and we're going to end the deposition now. Thank you.</p> <p>23 Off the record.</p> <p>24 THE WITNESS: Thank you very much.</p> <p>25 Thanks for all of you.</p>	<p style="text-align: right;">260</p> <p>1 STATE OF WASHINGTON )</p> <p>2 ) ss</p> <p>3 County of Snohomish )</p> <p>4 I, the undersigned Washington Certified Court</p> <p>5 Reporter, pursuant to RCW 5.28.010 authorized to</p> <p>6 Administer oaths and affirmations in and for the State of</p> <p>7 Washington, do hereby certify:</p> <p>8 That the annexed and foregoing deposition of FRED</p> <p>9 SILVERSTEIN, M.D. was taken before me and completed on</p> <p>10 September 29, 2010, and thereafter was transcribed under my</p> <p>11 direction;</p> <p>12 I further certify that according to CR 30 (e) the</p> <p>13 witness was given the opportunity to examine, read and sign</p> <p>14 the deposition after the same was transcribed, unless</p> <p>15 indicated in the record that the review was waived;</p> <p>16 I further certify that I am not a relative or employee</p> <p>17 of any such attorney or counsel, and that I am not</p> <p>18 financially interested in the said action or the outcome</p> <p>19 thereof;</p> <p>20 I further certify that the witness before examination</p> <p>21 was by me duly sworn to testify the truth, the whole truth</p> <p>22 and nothing but the truth;</p> <p>23 I further certify that the deposition, as transcribed,</p> <p>24 is a full, true and correct transcript of the testimony,</p> <p>25 including questions and answers, and all objections, motions</p> <p>and exceptions of counsel made and taken at the time of the</p> <p>foregoing examination and was prepared pursuant to Washington</p> <p>Administrative Code 308-14-135, the transcript preparation</p> <p>format guideline;</p> <p>I further certify that I am herewith securely sealing</p> <p>the said deposition and promptly delivering the same to</p> <p>Attorney MATTHEW MONTGOMERY.</p> <p>IN WITNESS WHEREOF, I have hereunto set my hand this</p> <p>6th day of October, 2010.</p> <p>_____ Connie Recob, Certified Court Reporter No. 2631 in and for the State of Washington, residing at Stanwood, Washington. My CCR certification expires 4/8/11.</p>



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Fred Silverstein

September 29, 2010

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1 DEPOSITION ERRATA SHEET

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3 Our Assignment No. Seattle 16128/San Diego 335512

4 Case Caption: ALASKA ELECTRICAL PENSION FUND vs. PHARMACIA

5

6 DECLARATION UNDER PENALTY OF PERJURY

7

8 I declare under penalty of perjury

9 that I have read the entire transcript of

10 my Deposition taken in the captioned matter

11 or the same has been read to me, and

12 the same is true and accurate, save and

13 except for changes and/or corrections, if

14 any, as indicated by me on the DEPOSITION

15 ERRATA SHEET hereof, with the understanding

16 that I offer these changes as if still under oath.

17

18 Signed on the \_\_\_\_\_ day of \_\_\_\_\_, 2010.

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22 FRED SILVERSTEIN, M.D.

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1 DEPOSITION ERRATA SHEET

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25 FRED SILVERSTEIN, M.D.

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